



# **PACE Manual**

## **Final Draft**

**December 1, 2010**

## **Programs of All-Inclusive Care for the Elderly (PACE) Manual**

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### **Table of Contents**

<a href="#"><u>Chapter 1 - Introduction to PACE</u></a>	3
<a href="#"><u>Chapter 2 - Administrative Requirements</u></a>	12
<a href="#"><u>Chapter 3 - Marketing</u></a>	24
<a href="#"><u>Chapter 4 - Enrollment and Disenrollment</u></a>	29
<a href="#"><u>Chapter 5 - Participant Rights and Restraint Policies</u></a>	43
<a href="#"><u>Chapter 6 - Services</u></a>	50
<a href="#"><u>Chapter 7 - Service Delivery Settings</u></a>	59
<a href="#"><u>Chapter 8 - IDT, Assessment &amp; Care Planning</u></a>	70
<a href="#"><u>Chapter 9 - Organization's Relationship with Health Care Providers</u></a>	86
<a href="#"><u>Chapter 10 - Quality Assessment and Performance Improvement</u></a>	100
<a href="#"><u>Chapter 11 - Grievances and Appeals</u></a>	116
<a href="#"><u>Chapter 12 - Medical Records Documentation</u></a>	122
<a href="#"><u>Chapter 13 - Payments to PACE Organizations</u></a>	129
<a href="#"><u>Chapter 14 - Coordination of Benefits</u></a>	138
<a href="#"><u>Chapter 15 - Organization Monitoring and Auditing</u></a>	147
<a href="#"><u>Chapter 16 - Sanctions, Enforcement Actions and Termination</u></a>	160
<a href="#"><u>Chapter 17 - Application and Waiver Processes, and Program Agreement Requirements</u></a>	166
<a href="#"><u>Appendix I - Glossary</u></a>	177

## Chapter 1 - Introduction to PACE

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### Table of Contents

<a href="#">1.1 History of PACE</a>	4
<a href="#">1.1.2 Demonstration Project History</a>	4
<a href="#">1.1.3 Legislative History</a>	5
<a href="#">1.2 Statutory and Regulatory Overview</a>	5
<a href="#">1.2.1 State Medicaid Plan Requirement</a>	6
<a href="#">1.2.2 Consultations with State Agency on Aging</a>	6
<a href="#">1.2.3 Interaction with Medicare Advantage</a>	6
<a href="#">1.2.4 Interaction with Medicare Part D</a>	7
<a href="#">1.2.5 Flexibility</a>	7
<a href="#">1.3 Overall Objective of PACE Model</a>	8
<a href="#">1.3.1 Overview of the PACE Program</a>	8
<a href="#">1.3.2 Organizations</a>	9
<a href="#">1.3.3 Eligibility and Benefits</a>	9
<a href="#">1.3.4 Payments to PACE Organizations</a>	10
<a href="#">1.3.5 Quality of Care</a>	10

## **1.1 History of PACE**

In the 1970's the federal and state governments became increasingly interested in the development of community-based services. As a result, waivers of federal Medicaid requirements allowed state governments to experiment with fee-for-service programs for frail elderly and disabled beneficiaries. One such program was the Programs of All-Inclusive Care for the Elderly (PACE), which was conceived and refined at On Lok Senior Health Services in San Francisco. On Lok enrollees were among the frailest elderly in the community, those considered most at risk or otherwise needing institutional placement to receive long-term care services. A demonstration of the On Lok model was initiated in 1991 and by 1992 there were ten, and later 15 PACE replication sites. The demonstration operated until PACE was established as a permanent Medicare program by the Balanced Budget Act of 1997 (BBA). The BBA authorized the coverage of PACE under the Medicare program and established PACE as a state plan option under Medicaid. As of November 2009, there were 70 PACE programs operational in 29 states. An updated list is available at: <http://www.cms.hhs.gov/PACE/LPPO/list.asp#TopOfPage>.

The PACE Protocol was first developed in 1990 as part of a cooperative effort involving staff from CMS then the Health Care Financing Administration Office of Research Development and Information, States participating in the PACE replication, and PACE sites, including On Lok Senior Health Services. Most of the features of PACE continued from the demonstration into the permanent program, including the focus on the targeted population, the frail elderly, and the capitated funding mechanism.

In September 2006, CMS awarded \$7.5 million in grant funds to organizations developing PACE in rural service areas. Fourteen organizations each received over \$500,000 for the establishment of a PACE program in their area. This grant program was initiated through the Deficit Reduction Act of 2005. The funding was available through September 30, 2008, and was provided to all fourteen grantees that met the requirements as a PACE provider as demonstrated through the PACE provider application approval process.

### **1.1.2 Demonstration Project History**

Section 603(c) of the Social Security Amendments of 1983 (Pub. L. 98-21), as extended by Section 9220 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99-272), authorized the original demonstration waiver for On Lok Senior Health Services in San Francisco. Section 9412(b) of the Omnibus Budget Reconciliation Act (OBRA) of 1986, Pub. Law 99-509, as amended by section 4118 of the OBRA of 1987 (Pub. L. 100-203), authorized the Secretary of HHS to grant waivers to organizations under a PACE demonstration project to determine whether the model of care developed by On Lok Senior Health Services could be replicated across the country (the number of sites was originally limited to 10, but section 4744(a)(1) of OBRA of 1990 (Pub. L. 101-508) authorized an increase to 15 demonstration sites). The PACE demonstration replicated a unique model of managed care service delivery for a small number of very frail community-dwelling elderly,

most of whom were dually eligible for Medicare and Medicaid coverage and all of whom were assessed as being eligible for nursing home placement according to the standards established by their respective States. The model of care included as core services the provision of adult day health care and multidisciplinary team case management, through which access to and allocation of all health services was controlled. Physician, therapeutic, ancillary and social support services were furnished in the participant's residence or on-site at the adult day health center, unless those locations were not feasible. Hospital, nursing home, home health, and other specialized services were furnished under contract. Financing of this model was accomplished through prospective capitation of both Medicare and Medicaid payments. Demonstration sites had been permitted by Section 4118(g) of OBRA of 1987 (Pub. Law 100–203) to assume full financial risk progressively over the initial three years, but that authority was removed by Section 4803(b)(1)(B) of the BBA.

### **1.1.3 Legislative History**

Section 4801 of the BBA (Pub. L. 105–33) authorized the establishment of PACE under the Medicare program by adding section 1894 to Title XVIII of the Social Security Act (the Act) which addresses Medicare payments to, and coverage of benefits under, PACE. Section 4802 of the BBA authorized the establishment of PACE as a State option under Medicaid by adding section 1934 to Title XIX of the Act, which directly parallels the provisions of Section 1894 and addresses Medicaid payments to, and coverage of benefits under, PACE. Section 4803 of the BBA addresses the timely issuance of regulations, expansion and transition for PACE demonstration project waivers, priority and special consideration in processing applications, and repeal of current PACE demonstration project waiver authority.

In addition, Sections 1894(a)(3)(B) and 1934(a)(3)(B) of the Act allowed private, for-profit entities to participate in PACE, subject to a demonstration waiver described in Sections 1894(h) and 1934(h) of the Act. Should for-profit entities wish to participate in PACE, they should apply for a demonstration waiver under Section 1894(h) and 1934(h) of the Act. While participating in the PACE for-profit demonstration, they must meet all requirements set forth in PACE regulations. The PACE organization is expected to retain all key administrative functions including marketing and enrollment, quality assurance and program improvement, and contracting for institutional providers and other key staff. On July 24, 2009, CMS issued a Federal Register Notice announcing a closing date of July 26, 2010 for submission of proposals for the PACE for-profit demonstration project.

## **1.2 Statutory and Regulatory Overview**

As discussed previously, section 1894 of the Act addresses Medicare payments to, and coverage of benefits under, PACE. Section 1934 of the Act addresses PACE as a State option under Medicaid for States electing PACE as an optional Medicaid benefit under section 1905(a)(26) of the Act. The regulations implementing these PACE statutory requirements are set forth in 42 CFR Part 460. This manual provides further guidance on the PACE program.

### **1.2.1 State Medicaid Plan Requirement**

The State Medicaid plan is the contract between the States and the Federal government under which States agree to administer the Medicaid program in accordance with Federal law and policy. The State plan preprint sets forth the scope of the Medicaid program, including groups covered, services furnished, and payment policy. When a State wants to change its State Medicaid plan, the State submits a “State Plan Amendment” (SPA), which must be approved by CMS in order for the State to receive Federal matching funds for the amended plan.

Section 1905(a)(26) of the Act, as added by Section 4802(a)(1) of the Balanced Budget Act (BBA), provides authority for States to elect PACE as an optional Medicaid benefit. The State plan electing the optional PACE program must be approved before we can approve an application for a PACE organization in that State.

To aid States in modifying their State plans, the CMS Center for Medicaid and State Operations developed an interim State plan preprint for PACE. A State Medicaid letter dated March 23, 1998, provided information and guidance to State Medicaid agencies on how to satisfy the SPA requirement. Additional directions for completing the SPA were provided in a State Medicaid Director letter that was issued November 9, 2000. The most current version of the State Plan preprint is available on the CMS PACE homepage: [http://www.cms.hhs.gov/PACE/04\\_InformationforStateAgencies.asp](http://www.cms.hhs.gov/PACE/04_InformationforStateAgencies.asp).

### **1.2.2 Consultations with State Agency on Aging**

Under the Older Americans Act, State Agencies on Aging were charged with the responsibility of promoting comprehensive, coordinated services and systems for older persons in their States. Consistent with this responsibility, State Agencies on Aging oversee important programs for home and community-based services, which are funded through Title III of the Older Americans Act, State revenues, and the Medicaid home and community-based waiver program. The State agencies also implement and oversee important planning, referral, case management, and quality assurance functions. In addition, State agencies are responsible for administering the State Long Term Care Ombudsman Program through which service quality in nursing homes and board and care homes are monitored in every State. Each State agency that administers the PACE program should regularly consult with their respective State Agency on Aging in order to avoid service duplication in the PACE service areas and to assure the delivery and quality of services to PACE participants.

### **1.2.3 Interaction with Medicare Advantage**

Although the PACE program has certain fundamental similarities to Medicare Advantage and managed care organizations, PACE is not a Medicare Advantage plan. The Balanced

Budget Act (BBA) established distinct requirements for the PACE program. PACE is similar to some Medicare Advantage options in these ways: it is capitated; it is risk-based; it provides managed care; and it is an elective option. However, PACE differs significantly from a Medicare Advantage plan in other ways such as: it is not available nationwide (only in a limited number of states); it includes statutory waivers that expand the scope of Medicare covered services; it is not available to all beneficiaries (only to a defined subset of frail elderly); and it is a joint Medicare/Medicaid program. The BBA in sections 1894(f)(3)(A) and 1934(f)(3)(A) of the Act directed CMS to consider some of the requirements established for Medicare Advantage programs while developing regulations for the PACE program relating beneficiary protections and program integrity.

#### **1.2.4 Interaction with Medicare Part D**

PACE organizations offer Medicare Part D prescription drug coverage. Persons who join a PACE program will get Part D-covered drugs and all other necessary medication from the PACE program. Persons in a PACE program do not need to join a separate Medicare Part D prescription drug plan. Joining a separate Medicare drug plan will cause a person to be disenrolled from the PACE program.

#### **1.2.5 Flexibility**

The PACE regulation which established the requirements for PACE organizations is based on the On Lok, Inc. Protocol. The Protocol provided authority for CMS and the State Administering Agency (the State Agency designated to administer the PACE program), to waive specific requirements of the Protocol, if, in their judgment, the following criteria were met:

- The intent of the requirements were met by the proposed alternative and safe and quality care would be provided;
- Written requests for waivers were required to be approved by CMS and the State Administering Agency before implementation of the proposed alternative.

We incorporated the requirement under the Protocol in the PACE regulations to the extent consistent with the BBA provisions in sections 1894 and 1934 of the Act. The intention was to allow some flexibility to promote PACE in rural and Tribal areas while maintaining consistency with the requirements for other PACE programs. The rationale for limited view of the flexibility provisions was based on our belief that all PACE demonstration programs were in compliance with the PACE protocol and, therefore, would need to make only minor changes in their operations to meet the PACE regulatory requirements. CMS intended to provide more flexibility to all PACE organizations once sufficient experience in administering the PACE program was achieved. However, CMS learned that although the early PACE demonstration programs initially complied with the Protocol, most of them modified the Protocol requirements as they expanded, using the flexibility authorized in the

Protocol. While many of these modifications were related to the allowable areas of service coverage and arrangement provisions, many others were not authorized by the flexibility clause in the Protocol. Furthermore, many of the later PACE demonstration programs also inappropriately exercised the flexibility clause in the Protocol, especially with regard to direct employment of staff. Finally, very few of the waivers were requested in writing or approved by CMS or the State Administering Agency before implementation. Subsequently CMS revised regulations on the waiver process in accordance with the requirements of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554).

[64 FR 66302 (Nov. 24, 1999) and 67 FR 61496 (Oct. 1, 2002)]

### **1.3 Overall Objective of PACE Model**

The Program of All-Inclusive Care for the Elderly (PACE) is an innovative model that provides a range of integrated preventative, acute care, and long-term care services to manage the often complex medical, functional, and social needs of the frail elderly. PACE was created as a way to provide clients, family, caregivers and professional health care providers the flexibility to meet a person's health care needs while continuing to live safely in the community.

The purpose of a PACE program is to provide pre-paid, capitated, comprehensive health care services that are designed to:

- Enhance the quality of life and autonomy for frail, older adults;
- Maximize dignity of and respect for older adults;
- Enable frail, older adults to live in their homes and in the community as long as medically and socially feasible; and
- Preserve and support the older adult's family unit.

#### **1.3.1 Overview of the PACE Program**

PACE is a capitated benefit for frail elders authorized by the Balanced Budget Act of 1997 (BBA) that features a comprehensive service delivery system and integrated Medicare and Medicaid financing. The program is modeled on the system of care developed by On Lok Senior Health Services in San Francisco, California and was tested through demonstration projects that began in the mid-1980s. The BBA established PACE as a permanent entity within the Medicare program and enables states to provide PACE services to Medicaid beneficiaries as a state plan option. Operationally, the PACE program is unique as a three-way partnership between the Federal government, the State, and the PACE organization.

### **1.3.2 Organizations**

A PACE organization is a not-for-profit, for-profit private or public entity that is primarily engaged in providing PACE services. For-profit entities operating PACE organizations do so under demonstration authority. The following characteristics also apply to a PACE organization. It must:

- Have a governing body or a designated person functioning as a governing body that includes participant representation;
- Be able to provide the complete service package regardless of frequency or duration of services;
- Have a physical site and staff to provide primary care, social services, restorative therapies, personal care and supportive services, nutritional counseling, recreational therapy, and meals;
- Have a defined service area;
- Have safeguards against conflict of interest;
- Have demonstrated fiscal soundness; and
- Have a formal Participant Bill of Rights; and
- Have a process to address grievances and appeals.

The PACE organization must not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, or source of payment.

### **1.3.3 Eligibility and Benefits**

Participants must be age 55 or older; reside in the PACE organization's service area; be certified as eligible for nursing home care by their state and be able to live safely in a community setting at the time of enrollment. Eligible beneficiaries who choose to enroll in PACE agree to forgo their usual sources of care and receive all their services through the PACE organization. (Additional information on Eligibility and Enrollment can be found in Chapter 4).

PACE provides participants all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team (IDT), as well as additional medically-necessary care and services not covered by Medicare and Medicaid. There are no limitations or condition as to amount, duration or scope of services and there are no deductibles, copayments,

coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid. The IDT assesses the participant's needs and develops a comprehensive care plan that meets the needs of its participants across all care settings on a 24 hour basis, each day of the year. Social and medical services are provided primarily in an adult day health care center, but are supplemented by in-home and referral services as needed.

The benefit package for all PACE participants includes: Primary Care, Hospital Care, Medical Specialty Services, Prescription Drugs (including Medicare Part D drugs), Nursing Facility Services, Emergency Services, Home Care, Physical Therapy, Occupational Therapy, Adult Day Health Care, Recreational Therapy, Meals, Dental Care, Nutritional Counseling, Social Services, Laboratory/X-Ray, Social Work Counseling, End of Life Care and Transportation. Hospital, Nursing Facility, Home Health, and other specialized services are generally furnished under contract. In most cases, the comprehensive service package permits participants to continue living at home rather than be institutionalized.

### **1.3.4 Payments to PACE Organizations**

PACE services are financed by combined Medicare and Medicaid prospective capitation payments, and, in some instances, through private premiums. PACE organizations receive a capitated monthly fee for each eligible enrollee, and combine these funds into a common pool from which providers pay health care expenses. This capitated financing allows PACE organizations to deliver all services participants need rather than be limited to those reimbursable under the Medicare and Medicaid fee-for-service systems. In exchange, PACE organizations assume full financial risk for all the health care services enrollees need.

As a Medicare program and a Medicaid state plan option, PACE organizations receive two capitation payments per month for dually eligible participants.

Medicare eligible participants who are not eligible for Medicaid pay monthly premiums equal to the Medicaid capitation amount and a premium for Medicare Part D drugs, but no deductibles, coinsurance, or other type of Medicare or Medicaid cost-sharing applies. For those participants eligible for Medicaid, but not Medicare, the state will pay the full cost to the PACE organizations. PACE providers assume full financial risk for participants' care without limits on amount, duration, or scope of services.

### **1.3.5 Quality of Care**

The PACE organization is required to develop, implement, maintain, and evaluate an effective data-driven quality assessment and performance improvement (QAPI) program. It is important that the QAPI program take into consideration the wide range of services furnished by the PACE organization. PACE organizations have the flexibility to develop the QAPI program that best meets their needs in order that they may fully meet the obligations of care for its participants. It is CMS' expectation that PACE organizations will operate a continuous QAPI program that does not limit activity to only selected kinds of services or

types of patients. The desired outcome of the QAPI requirement is that data-driven quality assessment serves as the engine that drives and prioritizes continuous improvements for all PACE organizations services.

## Chapter 2 - Administrative Requirements

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### Table of Contents

<a href="#"><u>2.1 Introduction</u></a>	14
<a href="#"><u>2.2 PACE Organizational Structure</u></a>	14
<a href="#"><u>2.2.1 Program Director</u></a>	14
<a href="#"><u>2.2.2 Medical Director</u></a>	15
<a href="#"><u>2.2.3 Organizational Chart</u></a>	15
<a href="#"><u>2.3 Governing Body</u></a>	16
<a href="#"><u>2.4 Participant Advisory Committee</u></a>	16
<a href="#"><u>2.4.1 Participant Representation on the Governing Body</u></a>	17
<a href="#"><u>2.5 Program Integrity</u></a>	17
<a href="#"><u>2.5.1 Persons with Criminal Convictions</u></a>	17
<a href="#"><u>2.5.2 Direct or Indirect Interest in Contracts</u></a>	17
<a href="#"><u>2.5.3 Disclosure Requirements</u></a>	18
<a href="#"><u>2.5.4 Privacy Policy</u></a>	18
<a href="#"><u>2.6 Fiscal Soundness</u></a>	20
<a href="#"><u>2.6.1 Fiscally Sound Operation</u></a>	20
<a href="#"><u>2.6.2 Insolvency Plan</u></a>	21
<a href="#"><u>2.6.3 Arrangements to Cover Expenses</u></a>	22
<a href="#"><u>2.7 Emergency and Disaster Preparedness</u></a>	22
<a href="#"><u>2.7.1 Emergencies Defined</u></a>	22
<a href="#"><u>2.7.2 Emergency Training</u></a>	23

<a href="#"><u>2.7.3 Availability of Emergency Equipment</u></a>	23
<a href="#"><u>2.7.4 Annual Test of Emergency and Disaster Plan</u></a>	23

## **2.1 Introduction**

The purpose of this chapter is to provide information about the requirements established relating to the organizational structure, the governing body and program integrity of the PACE organization as well as the relationships between entities. These requirements are essential to the PACE organization's ability to ensure the health and safety of the participants and provide a well functioning organizational environment in which appropriate care can occur.

## **2.2 Organizational Structure**

A PACE organization must be, or be a distinct part of, one of the following:

- An entity of city, county, State, or Tribal government;
- A private not-for-profit entity organized for charitable purposes under Section 501(c)(3) of the Internal Revenue Code of 1986. The entity may be a corporation, a subsidiary of a larger corporation, or a department of a corporation;
- A for-profit entity, subject to a demonstration waiver. CMS notes that sections 1894(a)(3)(B) and 1934(a)(3)(B) of the Act allow private, for-profit entities to participate in PACE, subject to a demonstration waiver described in section 1894(h) and 1934(h) of the Act. Should for-profit entities wish to participate in PACE, they should apply for a demonstration waiver under section 1894(h) and 1934(h) of the Act. CMS issued a Federal Register notice on July 24, 2009 announcing July 26, 2010 as the closing date for submission of proposals for the for-profit demonstration project for PACE. While participating in the PACE for-profit demonstration, they must meet all requirements set forth in PACE regulations. CMS explicitly stated that we would expect the PACE organization to retain all key administrative functions including marketing and enrollment, quality assurance and program improvement, and contracting for institutional providers and other key staff.

A potential PACE organization must supply evidence that core staff have been chosen and accepted specific key positions in their official application submission.

In the event of a change of ownership, CMS would apply the general provisions described in 42 CFR § 422.550 [Effect of change of ownership or leasing of facilities during term of contract.]

[42 CFR §§ 460.32, 460.60(a); 71 FR 71263 (Dec. 8, 2006)]

### **2.2.1 Program Director**

The organization must employ, or contract with in accordance with 42 CFR § 460.70, a program director who is responsible for oversight and administration of the entity.

The program director is responsible for the effective planning, organization, administration and evaluation of the organization's operations. The program director will also ensure that decisions about medical, social, and supportive services are not unduly influenced by the fiscal manager. The program director is responsible for ensuring that appropriate personnel perform their functions within the organization. The program director will inform employees and contract providers of all organization policies and procedures. If the PACE organization is part of a larger health system, the program director will clearly define and inform the PACE organization staff (employees and contractors) of the policies applicable to the PACE organization [42 CFR § 460.60].

[42 CFR § 460.60(b); 71 FR 71262 (Dec. 8, 2006)]

### **2.2.2 Medical Director**

The PACE organization must employ, or contract with in accordance with 42 CFR § 460.70, a medical director who is responsible for the delivery of participant care, for clinical outcomes, and for the implementation, as well as oversight, of the quality assessment and performance improvement program.

The medical director is responsible for achieving the best clinical outcomes possible for all participants. CMS expects the medical director to use the organization's data to demonstrate internal improvements in outcomes over time.

[42 CFR § 460.60(c); 71 FR 71263 (Dec. 8, 2006)]

### **2.2.3 Organizational Chart**

The organizational chart is requested at the time of application or expansion request and when there are changes in key personnel:

- The PACE organization must have a current organizational chart showing officials in the PACE organization and relationships to any other organizational entities;
- The chart for a corporate entity must indicate the PACE organization's relationship to the corporate board and to any parent, affiliate, or subsidiary corporate entities;
- A PACE organization planning a change in organizational structure must notify CMS and the State Administering Agency, in writing, at least 14 days before the change takes effect.

NOTE: A change in organizational structure is one that may affect the philosophy, mission, and operations of the PACE organization and impact care delivery to participants. This would include any change in ownership, relationships to another corporate board and to any parent, affiliate, or subsidiary corporate entities, the PACE governing body, its officials, program director and medical director.

[42 CFR §§ 460.32(a)(4), 460.60(d)]

## **2.3 Governing Body**

The governing body must create and foster an environment that provides quality care that is consistent with the participant needs and the program mission.

A PACE organization must be operating under the control of an identifiable governing body (for example, a board of directors) or a designated person functioning as a governing body with full legal authority and responsibility for the following:

- Governance and operation of the organization;
- Development of policies consistent with the mission;
- Management and provision of all services, including the management of contractors;
- Establishment of personnel policies that address adequate notice of termination by employees or contractors with direct patient care responsibilities. These policy and procedures need to be in compliance with local, state and federal guidelines;
- Fiscal operations;
- Development of policies on participant health and safety, including a comprehensive, systemic operational plan to ensure the health and safety of participants;
- Quality assessment and performance improvement program (QAPI). The purpose of this requirement is to link the development, implementation, and coordination of the ongoing QAPI program with all aspects of the PACE program.

[42 CFR § 460.62(a); 71 FR 71264 (Dec. 8, 2006)]

## **2.4 Participant Advisory Committee**

A PACE organization must establish a participant advisory committee to provide advice to the governing body on matters of concern to participants. Participants and representatives of participants must constitute a majority of the membership of this committee. The participant

advisory committee must provide the liaison to the governing body with meeting minutes that include participant issues.

[42 CFR § 460.62(b)]

#### **2.4.1 Participant Representation on the Governing Body**

A PACE organization must ensure participant representation on issues related to participant care. This shall be achieved by having a participant representative on the governing body (this representation may take the form of a participant, his/her caregiver, or an advisory committee member). The participant representative is a liaison of the participant advisory committee to the PACE organization governing body. The participant representative must present issues from the participant advisory committee to the governing body.

[42 CFR § 460.62(c)]

### **2.5 Program Integrity**

#### **2.5.1 Persons with Criminal Convictions**

A PACE organization must not employ individuals or contract with organizations or individuals:

- Who have been excluded from participation in the Medicare or Medicaid programs;
- Who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, other health insurance or health care programs, or social service programs under Title XX of the Act, or
- In any capacity where an individual's contact with participants would pose a potential risk because the individual has been convicted of physical, sexual, drug, or alcohol abuse [42 CFR § 460.68(3)].

Verification of criminal background check may be done through a database check such as Department of Justice or State criminal background databases. The PACE organization will maintain a copy of this verification in the employee's personnel record, and this verification needs to be done annually or at some other duration established by CMS.

[42 CFR § 460.68(a)]

#### **2.5.2 Direct or Indirect Interest in Contracts**

The PACE organization shall identify members of its governing body or any immediate family member having direct or indirect interest in any contract that supplies any

administrative or care-related service or materials to the PACE organization. PACE organizations must develop policies and procedures for handling any direct or indirect conflict of interest by a member of the governing body or by the member's immediate family. In the event of a direct or indirect conflict of interest by a member of the PACE organization's governing body or his or her immediate family member, the board member must (1) fully disclose the exact nature of the conflict to the board of directors and have the disclosure documented; and (2) recuses himself or herself from discussing, negotiating, or voting on any issue or contract that could result in an inappropriate conflict.

Examples of indirect interests are holdings in the name of the spouse, dependent child, or other relative who resides with the member of the governing body. These requirements are intended to protect participants by preventing fraud under Medicare and Medicaid by preventing members of the governing body with conflicts of interest from inappropriately influencing PACE organization decisions.

CMS remains committed to working with rural and Tribal communities to help them address the challenges of developing successful PACE programs. Due to potential limited availability of individuals willing to and capable of performing key functions for the PACE organization, there is a special need for flexibility in rural and Tribal areas, and CMS remains committed to allowing waivers to promote PACE in medically underserved areas.

[42 CFR § 46.68(b); 71 FR 71269 (Dec. 8, 2006)]

### **2.5.3 Disclosure and Recusal Requirements**

A PACE organization must have a formal process in place to gather information related to persons with criminal convictions (section 2.5.1 above) and direct or indirect interest in contracts (section 2.5.2 above) and must be able to respond in writing to a request for information from CMS within a reasonable amount of time.

[42 CFR § 460.68(c)]

### **2.5.4 Privacy Policy**

A PACE organization must abide by all applicable Federal and State laws regarding confidentiality and disclosure for mental health records, medical records and other participant health information (PHI) (See <http://www.cms.hhs.gov/HIPAAgenInfo/Downloads/HIPAAALaw.pdf> to obtain further information on current HIPAA regulations.

[42 CFR § 460.200(e)(4)]

### **De-identified Health Information and Limited Data Set:**

If it is necessary to disclose PHI, there are two methods to accomplish the release of information. The organization may de-identify the information. The de-identified information is not PHI because it does not identify an individual and there is no reasonable basis to believe that the information can be used to identify an individual. De-identified information, therefore, is outside the purview of the HIPAA privacy standards.

Under the HIPAA privacy requirements there are two ways to de-identify PHI:

- The organization may de-identification in accordance with “generally accepted statistical and scientific principles and methods”; or
- The organization may remove all identifiers of an individual or of relatives, employers or household members of the individual listed in the safe harbor method in the regulation:
  - o Names;
  - o All geographic subdivisions smaller than a State (see reg. for further explanation);
  - o All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death: and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
  - o Telephone numbers;
  - o Fax numbers;
  - o Electronic mail addresses;
  - o Social security numbers;
  - o Medical record numbers;
  - o Health plan beneficiary numbers;
  - o Account numbers;
  - o Certificate/license numbers;
  - o Vehicle identifiers and serial numbers, including license plate numbers;

- o Device identifiers and serial numbers;
- o Web URLs;
- o IP address numbers;
- o Biometric identifiers, including finger and voice prints;
- o Full face photographic images and any comparable images; and
- o Any other unique identifying number, characteristic, or code.

Additionally, the PACE organization does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is the subject of the information.

The organization may assign a code or other means of record identification to allow information de-identified to be re-identified.

The PACE organization should have the following HIPAA Compliance for Safeguarding PHI:

- The organization has a contingency plan and disaster recovery plan for all PHI;
- The organization has security policy and procedures for data

[45 CFR § 164.514(a) and (b)]

## **2.6 Fiscal Soundness**

### **2.6.1 Fiscally Sound Operation**

A PACE organization must have a fiscally sound operation, as demonstrated by the following:

- Total assets greater than total unsubordinated liabilities;
- Sufficient cash flow and adequate liquidity to meet obligations as they become due;
- A net operating surplus or a financial plan for maintaining solvency that is satisfactory to CMS and the State Administering Agency.

A PACE organization under the three-year trial period is required to submit quarterly financial statements to CMS within 45 days from the end of each quarter of the PACE organization's fiscal year. After the trial period, if CMS or the State Administering Agency determines that an organization's performance requires more frequent monitoring and oversight due to concerns about fiscal soundness, CMS or the State Administering Agency may require a PACE organization to submit monthly or quarterly financial statements, or both. The financial statements shall include a balance sheet, income statement, and a cash flow statement. In addition to the quarterly financial statements, PACE organizations under a three year trial period are required to submit their latest independently prepared audit report containing their audited financial statements along with the auditor's opinion and auditor notes. PACE organizations operating within larger sponsoring entities must also submit their sponsoring entities' independently prepared audit report. The audit reports are due within 180 days from an organization's fiscal year end.

CMS no longer accepts hardcopy documentation. Instead, PACE organizations are required to upload a PDF or zip file of their quarterly financial statements and annual audit reports to the fiscal soundness module within the Health Plan Management System (HPMS).

In addition to the financial statements PACE organizations must upload 12 financial data elements (taken from the audited and quarterly financial statements) 9 along with the financial statements. The fiscal soundness module will not accept the financial statements if the data elements are not uploaded at the same time.

If you cannot file the financial information by the regulatory deadlines shown under CFR § 460.208 (a), you must contact CMS before the prescribed due date. Failure to submit on time without notifying CMS places your company in non-compliance status and could result in your company receiving a non-compliance letter with the requirement of a corrective action plan to resolve the deficiency.

[42 CFR §§ 460.80(a), 460.80(b) and 460.208(c)]

### **2.6.2 Insolvency Plan**

The PACE organization must have a documented plan in the event of insolvency, approved by the Centers for Medicare Medicaid Services, and the State Administering Agency, which provides for the following:

- Continuation of benefits for the duration of the period for which capitation payment has been made;
- Continuation of benefits to participants who are confined in a hospital on the date of insolvency until their discharge;

- Protection of participants from liability for payment of fees that are the legal obligation of the PACE organization.

[42 CFR §§ 460.80(b)]

### **2.6.3 Arrangements to Cover Expenses**

A PACE organization must demonstrate that it has arrangements to cover expenses in the amount of at least the sum of the following in the event it becomes insolvent:

- One month's total capitation revenue to cover expenses the month before insolvency;
- One month's average payment to all contractors, based on the prior quarter's average payment, to cover expenses the month after the date it declares insolvency or ceases operation;
- Arrangements to cover expenses may include, but are not limited to, the following:
  - o Insolvency insurance or reinsurance;
  - o Hold harmless arrangement;
  - o Letters of credit, guarantees, net worth, restricted State reserves, or State law provisions.

[42 CFR § 460.80(c)]

## **2.7 Emergency and Disaster Preparedness**

The PACE organization must establish, implement, and maintain documented procedures to manage medical and nonmedical emergencies and disasters that are likely to threaten the health or safety of the participants, staff, or the public. Additional information on requirements regarding emergencies can be found in Chapter 7 of the PACE Manual.

[42 CFR § 460.72(c)(1)]

### **2.7.1 Emergencies Defined**

Emergencies include, but are not limited to, the following:

- Fire;
- Equipment, water, or power failure;

- Care-related emergencies;
- Natural disasters likely to occur in the organization's geographic area (An organization is not required to develop emergency plans for natural disasters that typically do not affect its geographic location).

[42 CFR § 460.72(c)(2)]

### **2.7.2 Emergency Training**

A PACE organization must provide appropriate training and periodic orientation to all staff (employees and contractors) and participants to ensure that staff demonstrate a knowledge of emergency procedures, including informing participants what to do, where to go, and whom to contact in case of an emergency.

[42 CFR § 460.72(c)(3)]

### **2.7.3 Availability of Emergency Equipment**

Emergency equipment, including easily portable oxygen, airways, suction and emergency drugs, along with staff who know how to use the equipment, must be on the premises of every center at all times and be immediately available. The organization must have a documented plan to obtain emergency medical assistance from sources outside the center when needed.

[42 CFR § 460.72(4)]

### **2.7.4 Annual Test of Emergency and Disaster Plan**

At least annually, a PACE organization must actually test, evaluate and document the effectiveness of its emergency and disaster plans.

[42 CFR § 460.72(c)(5)]

## Chapter 3 – PACE Marketing

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### Table of Contents

<a href="#"><u>3.1 Introduction</u></a>	25
<a href="#"><u>3.2 General Marketing Requirements</u></a>	25
<a href="#"><u>3.2.1 Marketing Plan</u></a>	26
<a href="#"><u>3.2.2 Non-English Materials</u></a>	26
<a href="#"><u>3.3 Review Process</u></a>	26
<a href="#"><u>3.3.1 Timeframes</u></a>	27
<a href="#"><u>3.3.2 Approval or Disapproval</u></a>	27
<a href="#"><u>3.3.3 Deemed Approval</u></a>	27
<a href="#"><u>3.4 Prohibited Marketing Activities</u></a>	27
<a href="#"><u>3.5 Part D Information</u></a>	28

### **3.1 Introduction**

PACE organizations must inform the general public about their programs. This chapter provides guidance to the PACE organizations on CMS marketing requirements.

It is important to note that the marketing guidance set forth in this document is subject to change as communication technology and industry marketing practices continue to evolve. Moreover, the examples of marketing materials and promotional activities given in these guidelines are not all-inclusive. PACE organizations should apply the principles outlined in these guidelines to all relevant decisions, situations, and materials. Any new rule-making or interpretative guidance (e.g., Health Plan Management System (HPMS) guidance memoranda) may update the marketing guidance provided here, and sound judgment and consultation with CMS Account Managers should be used in situations where new guidance updates the guidance provided in this document. This manual will be periodically updated to incorporate new guidance.

### **3.2 General Marketing Requirements**

All marketing material must be free of material inaccuracies, misleading information and misrepresentations about the PACE Program as governed by 42 CFR § 460.82.

All marketing materials must inform a potential participant that he or she must receive all needed health care services (other than emergency services), including primary care and specialist physician services from the PACE organization or from an entity authorized by the PACE organization.

Marketing materials must also clearly state that PACE participants may be fully and personally liable for the costs of unauthorized or out-of-network services.

Specifically, a PACE organization must inform the public about its program and give prospective participants the following written information:

- An adequate description of the PACE organization's enrollment and disenrollment policies and requirements;
- PACE enrollment procedures;
- Description of benefits and services;
- Premium information, if applicable;
- Other information necessary for a prospective participant to make an informed decision about enrollment.

Font size equivalent to or larger than Times New Roman 12-point may be used for easier reading.

[42 CFR § 460.82(a)(2) and (d)]

### **3.2.1 Marketing Plan**

The PACE organization is required to establish, implement and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking effectiveness.

Marketing plans and associated policies and procedures are submitted by the PACE organization and reviewed by the State Administering Agency and CMS as part of the provider application. These materials are also reviewed during onsite monitoring visits for any significant revisions to the marketing plan.

[42 CFR § 460.82(f); 71 FR 71279 (Dec. 8, 2006)]

### **3.2.2 Non-English Materials**

The PACE organization must furnish printed marketing materials to prospective and current participants in English and in any other principal languages of the community and in Braille if necessary.

The determination of the principle languages of a PACE organization's service area is a State determination. Therefore, we recommend that interested parties contact their State for specific information.

[42 CFR § 460.82(c); 71 FR 71279 (Dec. 8, 2006)]

## **3.3 Review Process**

All marketing material must be reviewed and approved by CMS and the State Administering Agency prior to their use, publication or distribution by the PACE organization.

CMS reviews initial marketing information as part of an entity's application for approval as a PACE organization, and approval of the application includes approval of marketing information.

After an organization is under a PACE program agreement, any new or revised marketing materials must be submitted for review by CMS and the SAA.

[42 CFR § 460.82(b)(1)]

### **3.3.1 Timeframes**

Once a PACE organization is under a PACE Agreement, any revisions to existing marketing information and new information are subject to certain time periods. CMS has 45 days to review and approve or disapprove any new or revised marketing pieces submitted by the PACE organization. The 45-day review clock begins on the date the PACE organization submits the marketing material in HPMS for CMS to review, or the date that the CMS Regional Office receives the material in hard copy.

The 45-day review period applies each time an individual piece of marketing material is submitted to CMS for review. For example, if marketing material is submitted to CMS for review and, on the 32<sup>nd</sup> day, CMS renders the decision of disapproved, upon correcting the material's deficiencies and resubmitting the piece, the 45-day clock starts anew.

[42 CFR § 460.82(b)(3)(i)]

### **3.3.2 Approval or Disapproval**

CMS approves or disapproves marketing information within 45 days after CMS receives the information from the organization.

Notification of approval or disapproval will be sent to the PACE organization by CMS Regional office following agreement by the State Administering Agency.

Marketing materials, once approved, remain approved until either the material is altered by the PACE organization or conditions change such that the material is no longer accurate. However, CMS, in agreement with the State Administering Agency may, at any time, require a PACE organization to change any previously approved marketing materials if found to be inaccurate, even if the original submission was accurate at the time of approval.

[42 CFR § 460.82(b)(1)]

### **3.3.3 Deemed Approval**

Marketing information is deemed approved, and the organization can distribute it, if CMS and the State administering agency do not disapprove the marketing material within the 45-day review period.

## **3.4 Prohibited Marketing Activities**

A PACE organization must ensure that its employees or its agents do not conduct prohibited marketing activities which include the following:

- Discrimination of any kind among individuals who meet PACE eligibility standards, except that marketing may be directed to individuals eligible for PACE by reason of their age;
- Activities that could mislead or confuse potential participants, or misrepresent the PACE organization, CMS, or the State Administering Agency;
- Activities that involve gifts or payments to induce enrollment. For example, offering gifts to potential enrollees that attend a marketing presentation is permitted as long as these gifts are of a nominal value and are provided whether or not the individual enrolls in the PACE program. The gift cannot be a cash gift or be readily converted into cash regardless of the amount;
- Contracting outreach efforts to individuals or organizations whose sole responsibility involves direct contact with the elderly to solicit enrollment; or
- Unsolicited door-to-door marketing.

A prospective PACE organization is not permitted to market PACE services until they have an approved application and signed program agreement.

[42 CFR § 460.82(b)(1) and (e); 71 FR 71278 (Dec. 8, 2006)]

### **3.5 Part D Information**

PACE organizations must inform potential members that they offer Medicare Part D prescription drug coverage. Informational materials must also inform participants that if they are in a PACE program they cannot be enrolled in a separate Medicare prescription drug plan and that joining a separate Medicare drug plan will cause them to lose their PACE health and prescription drug benefits.

## Chapter 4 - PACE Enrollment and Disenrollment

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### Table of Contents

<a href="#"><u>4.1 Introduction</u></a>	31
<a href="#"><u>4.1.1 Eligibility for Enrollment</u></a>	31
<a href="#"><u>4.1. 1.1 Eligibility Criteria</u></a>	31
<a href="#"><u>4.1.1.2 End Stage Renal Disease (ESRD)</u></a>	31
<a href="#"><u>4.1.1.3 Hospice</u></a>	32
<a href="#"><u>4.2 Discrimination against Beneficiaries Prohibited</u></a>	32
<a href="#"><u>4.3 Enrollment</u></a>	32
<a href="#"><u>4.3.1 Eligibility Determination</u></a>	32
<a href="#"><u>4.3.2 Denial of Enrollment</u></a>	33
<a href="#"><u>4.3.3 Enrollment of Medicaid Pending Individuals</u></a>	34
<a href="#"><u>4.3.4 Initial IDT Assessment</u></a>	34
<a href="#"><u>4.3.5 Enrollment Agreement</u></a>	35
<a href="#"><u>4.4 Disenrollments</u></a>	37
<a href="#"><u>4.4.1 Documentation of Disenrollment</u></a>	37
<a href="#"><u>4.4.2 Disenrollment Process</u></a>	38
<a href="#"><u>4.4.2.1 Voluntary Disenrollment</u></a>	38
<a href="#"><u>4.4.2.2 Involuntary Disenrollment</u></a>	38
<a href="#"><u>4.4.3 Additional Written Evidence of Involuntary Disenrollment for Disruptive or Threatening Behavior</u></a>	40
<a href="#"><u>4.4.4 Role of State Administering Agency</u></a>	40

<a href="#"><u>4.5 Reinstatement in other Medicare and Medicaid Programs</u></a>	41
<a href="#"><u>4.5.1 General Requirements</u></a>	41
<a href="#"><u>4.5.2 Access to MA and Medigap Coverage following Disenrollment</u></a>	41
<a href="#"><u>4.5.3 Enrollment/Disenrollment of Hospitalized Beneficiaries</u></a>	41
<a href="#"><u>4.6 Reinstatement in PACE</u></a>	42

## **4.1 Introduction**

This chapter discusses eligibility criteria and the enrollment process for the PACE program as provided in 42 CFR § 460.150. The eligibility criterion includes a requirement that a PACE eligible individual meet a specific level of care which is determined by the State Administering Agency and varies from state to state. State enrollment processes are separate from the processes identified below. PACE organizations should consult their State Administering Agency for instruction.

### **4.1.1 Eligibility for Enrollment**

#### **4.1.1.1 Eligibility Criteria**

To enroll in a PACE program, an individual must meet the following eligibility requirements listed in the Program Agreement:

- Be 55 years of age or older;
- Be determined by the State Administering Agency to need the level of care required under the State Medicaid plan for coverage of nursing facility services;
- Reside in the PACE organization's service area;
- Be able to live in a community setting at the time of enrollment without jeopardizing his/her health or safety based on criteria set forth in the program agreement;
- Meet any additional program-specific eligibility conditions imposed under its respective PACE Program Agreement;
- Not be concurrently enrolled in any other Medicare Advantage, Medicare Prescription Drug, or Medicaid prepayment plan, or optional benefit, such as a 1915c Home and Community Based Services waiver or the Medicare Hospice benefit.

A potential participant is not required to be a Medicare beneficiary or Medicaid recipient. A PACE enrollee may be but is not required to be, any or all of the following: (1) entitled to Medicare Part A; (2) enrolled under Medicare Part B; (3) eligible for Medicaid.

[42 CFR § 460.150]

#### **4.1.1.2 End Stage Renal Disease (ESRD)**

Individuals with End Stage Renal Disease (ESRD) are among the most frail and complex persons to care for. The PACE care delivery model is well-suited to meeting the needs of this

population and it is not appropriate to deny enrollment to these individuals solely based on their ESRD status.

[71 FR 71310 (Dec. 8, 2006)]

#### **4.1.1.3 Hospice**

Since comprehensive care is provided to PACE participants, those participants who need end-of-life care will receive the appropriate medical, pharmaceutical, and psychosocial services through the PACE organization. If a participant specifically wants to elect the hospice benefit from a certified hospice organization, the participant must voluntarily disenroll from the PACE program. The PACE organization will work with the State Administering Agency and CMS to facilitate the election of the hospice benefit and will work with the elected hospice organization to coordinate the transition of care.

### **4.2 Discrimination against Beneficiaries Prohibited**

The PACE organization must not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation or source of payment. Each PACE organization must agree to meet all applicable requirements under Federal, State and local laws and regulations including provisions of the Civil Rights Act, the Age Discrimination Act and the Americans with Disabilities Act. These requirements include, but are not limited to, all requirements contained in the regulations implementing those Acts.

[42 CFR §§ 460.32(a)(2), 460.98(b)(3)]

### **4.3 Enrollment**

#### **4.3.1 Eligibility Determination**

Intake is an intensive process during which PACE staff members make one or more visits to a potential participant's place of residence and the potential participant makes one or more visits to the PACE center. At a minimum, the intake process must include the following activities:

- The PACE staff must explain to the potential participant and his or her representative or caregiver the following information:
  - The PACE program, using a copy of the enrollment agreement, specifically references the elements of the agreement, including but not limited to § 460.154(e), (i) through (m), and (r);

- The requirement that the PACE organization would be the participant's sole service provider and clarification that the PACE organization guarantees access to services, but not to a specific provider;
- A list of the employees of the PACE organization who furnish care and the most current list of contracted health care providers;
- Monthly premiums, if any;
- Any Medicaid spenddown obligations;
- Post-eligibility treatment of income;
- The potential participant must sign a release to allow the PACE organization to obtain his or her medical and financial information and eligibility status for Medicare and Medicaid;
- The State Administering Agency must assess the potential participant, including any individual who is not eligible for Medicaid, to ensure that he or she needs the level of care required under the State Medicaid plan for coverage of nursing facility services, which indicates that the individual's health status is comparable to the health status of individuals who have participated in the PACE demonstration waiver programs.

The PACE staff must assess the potential participant to ensure that he or she can be cared for appropriately in a community setting and that he or she meets all requirements for PACE eligibility. This involves an assessment of the individual's care support network as well as the individual's health condition to determine whether or not his or her health or safety would be jeopardized by living in a community setting. The criterion for determining if an individual is able to live safely in the community is established, and must be approved, by the State. If it is determined that the prospective PACE enrollee's health or safety would be jeopardized by remaining in a community setting, the PACE organization should deny enrollment. The prospective enrollee will be notified by the PACE organization of any appeal rights.

[42 CFR § 460.152(a); 71 FR 71309 (Dec. 8, 2006)]

#### **4.3.2 Denial of Enrollment**

When an enrollment is denied because his or her health or safety would be jeopardized by living in a community setting, the PACE organization is required to complete the following steps:

- Notify the individual in writing of the reason for enrollment denial;

- Refer the individual to alternative services as appropriate;
- Maintain supporting documentation of the reason for the denial; and,
- Notify CMS and the State Administering Agency and make the documentation available for review. Notification to CMS can be accomplished through reporting the Data Elements for monitoring in HPMS.

[42 CFR § 460.152(b)]

### **4.3.3 Enrollment of Individuals Pending Medicaid Eligibility**

Eligibility to enroll in a PACE program is not restricted to an individual who is either a Medicare beneficiary or Medicaid recipient. During the enrollment process the applicant must sign a release to allow the PACE organization to obtain his or her medical and financial information and eligibility status for Medicare and Medicaid. The PACE organization is required to include any Medicaid spend down obligations in the enrollment agreement. CMS requires that that information regarding post eligibility treatment of income is also included in the enrollment agreement. As an additional participant protection, PACE organizations are required to review post-eligibility treatment of income with prospective enrollees as determined and calculated by the state.

[42 CFR § 460.152(a)(2) and (g)]

### **4.3.4 Initial Interdisciplinary Team (IDT) Assessment**

An initial comprehensive assessment is performed by the Interdisciplinary Team (IDT) on each participant independent of any pre-enrollment screening by the IDT. This assessment must be completed promptly following enrollment. The eight IDT members who conduct the initial assessment in person are the primary care physician, registered nurse, master's level social worker, dietitian, physical therapist, occupational therapist, recreational therapist or activities coordinator, and home care coordinator. The discipline-specific assessment of the participant's health and social status includes, but is not limited to, physical and cognitive function and ability, medication use, participant and caregiver preferences for care, socialization and availability of family support, current health status and treatment needs, nutritional status, home environment including access and egress, participant behavior, psychosocial status, medical and dental status, and participant language. The IDT may identify other healthcare specialists that are required to conduct additional assessments outside the IDT members' expertise or scope of practice. On completion of the assessments, the IDT promptly consolidates the discipline-specific assessments into a single plan of care for each participant through discussion in team meetings and consensus of the entire IDT. While "promptly" is not defined in the regulation, it is expected that the plan of care should take no longer than ten business days of completing the assessments. In developing the plan of care, female participants must be informed that they are entitled to choose a qualified

specialist for women's health services from the PACE organization's network to furnish routine or preventive women's health services.

[42 CFR § 460.104(a) and (b)]

#### **4.3.5 Enrollment Agreement**

The PACE-eligible prospective enrollee (or legal representative) must agree to several enrollment conditions including, but not limited to: having the PACE organization and its provider network as the sole provider of services; giving signed consent for the PACE organization to obtain medical and financial information to verify eligibility; and, agreeing to any applicable monthly premiums or Medicaid spend-down obligations. If the prospective PACE enrollee meets the eligibility requirements and signs the PACE enrollment agreement, the effective date of enrollment in the PACE program is on the first day of the calendar month following the date the PACE organization receives the participant's signed enrollment agreement. The PACE organization must submit a timely and accurate enrollment transaction to complete the enrollment in CMS systems. The enrollment agreement must, at a minimum, contain the following information:

- Applicant's name, sex, and date of birth;
- Medicare beneficiary status (Part A, Part B, or both) and number, if applicable;
- Medicaid recipient status and number, if applicable;
- Information on other health insurance, if applicable;
- Conditions for enrollment and disenrollment in PACE;
- Description of participant premiums, if any, and procedures for payment of premiums;
- Notification that a Medicaid participant and a participant who is eligible for both Medicare and Medicaid are not liable for any premiums, but may be liable for any applicable spend down liability and any amounts due under the post-eligibility treatment of income process;
- Notification that a Medicare participant may not enroll or disenroll at a Social Security office;
- Notification that enrollment in PACE results in disenrollment from any other Medicare or Medicaid prepayment plan or optional benefit. Electing enrollment in any other Medicare or Medicaid prepayment plan or optional benefit, including the

hospice benefit or Medicare Part D plan, after enrolling as a PACE participant, is considered a voluntary disenrollment from PACE;

- Information on the consequences of subsequent enrollment in other optional Medicare or Medicaid programs following disenrollment from PACE;
- Description of PACE services available, including all Medicare and Medicaid covered services, and how services are obtained from the PACE organization;
- Description of the procedures for obtaining emergency and urgently needed out-of-network services;
- The participant Bill of Rights;
- Information on the process for grievances and appeals and Medicare/Medicaid phone numbers for use in appeals;
- Notification of a participant's obligation to inform the PACE organization of a move or lengthy absence from the organization's service area;
- An acknowledgment by the applicant or representative that he or she understands the requirement that the PACE organization must be the applicant's sole service provider;
- A statement that the PACE organization has an agreement with CMS and the State Administering Agency that is subject to renewal on a periodic basis and, if the agreement is not renewed, the program will be terminated;
- The applicant's authorization for disclosure and exchange of personal information between CMS, its agents, the State Administering Agency, and the PACE organization;
- The effective date of enrollment;
- The signature of the applicant or his or her designated representative and the date.

After the participant signs the enrollment agreement, the PACE organization must give the participant the following:

- A copy of the enrollment agreement;
- A PACE membership card;

- Emergency information to be posted in his or her home identifying the individual as a PACE participant and explaining how to access emergency services;
- Stickers for the participant's Medicare and Medicaid cards, as applicable, which indicate that he or she is a PACE participant and which include the phone number of the PACE organization.

If there are changes in the enrollment agreement information at any time during the participant's enrollment, the PACE organization must meet the following requirements:

- Give an updated copy of the information to the participant;
- Explain the changes to the participant and his or her representative or caregiver in a manner they understand.

[42 CFR §§ 460.152(a)(1) and (2), 460.154, 460.156, and 460.158]

#### **4.4 Disenrollments**

There are only three reasons a participant can be disenrolled from a PACE program:

- Death;
- Voluntary disenrollment, (which would include enrollment by a participant into another Medicare Plan); or,
- Involuntary disenrollment by the PACE organization due to cause.

[42 CFR § 460.160(a)]

##### **4.4.1 Documentation of Disenrollment**

A PACE organization must meet the following requirements:

- Have a procedure in place to document the reasons for all voluntary and involuntary disenrollments;
- Make documentation available for review by CMS and the State Administering Agency;
- Use the information on voluntary disenrollments in the PACE organization's internal Quality Assessment and Performance Improvement (QAPI) program.

[42 CFR § 460.172]

#### **4.4.2 Disenrollment Process**

The PACE organization must take the following actions upon voluntary or involuntary disenrollment or death of a participant:

- Complete the disenrollment as expeditiously as allowed under Medicare and Medicaid;
- Coordinate the disenrollment date between Medicare and Medicaid as applicable;
- Give reasonable advance notice to the participant about disenrollment;
- Submit the disenrollment transaction to CMS systems in a timely and accurate manner.

The PACE organization must continue to provide all needed services, and the PACE participant must continue to use the PACE organization's services and pay any premiums, until the date the enrollment is actually terminated. The disenrollment date will be coordinated between Medicare and Medicaid for a participant who is dually eligible. No disenrollment will become effective until the participant is appropriately reinstated into other Medicare and Medicaid programs and alternative services are arranged.

[42 CFR § 460.166(a) and (b)]

##### **4.4.2.1 Voluntary Disenrollment**

Enrollment in the PACE program continues until the participant's death regardless of changes in health status unless the participant voluntarily disenrolls or the PACE organization involuntarily disenrolls the participant for strictly defined reasons. A PACE participant may voluntarily disenroll from the program without cause at any time [42 CFR § 460.160 and 42 CFR § 460.162]. The disenrollment date will be coordinated between Medicare and Medicaid for a participant who is dually eligible. No disenrollment will become effective until the participant is appropriately reinstated into other Medicare and Medicaid programs and alternative services are arranged.

[42 CFR § 460.162]

##### **4.4.2.2 Involuntary Disenrollment**

The PACE organization may involuntarily disenroll a participant only for any of the following reasons:

- Failure to Pay. Any participant who fails to pay, or make satisfactory arrangements to pay any premiums due, to the PACE organization after a thirty-day grace period;

- **Disruptive or Threatening Behavior.** A participant engages in disruptive or threatening behavior. Such behavior is defined as the following:
  - o Behavior that jeopardizes the participant’s own health or safety, or the safety of others; or
  - o Consistent refusal to comply with an individual plan of care or the terms of the PACE enrollment agreement by a participant with decision-making capacity. Note that a PACE organization may not involuntarily disenroll a PACE participant on the grounds that the participant has engaged in noncompliant behavior related to an existing mental or physical condition unless the participant’s behavior is jeopardizing his or her health or safety or that of others. Noncompliant behavior includes repeated noncompliance with medical advice and repeated failure to keep appointments;
- **Relocation Outside of the Service Area.** The participant moves out of the PACE program service area or is out of the service area for more than 30 consecutive days without PACE organization concurrence;
- **Non-renewal or Termination of Program Agreement.** The PACE organization’s program agreement with CMS and the State Administering Agency is not renewed or terminated;
- **Inability to Provide Services.** The PACE organization is unable to offer healthcare services due to the loss of state licenses or contracts with outside providers;
- **Ineligibility:** It is determined that the participant no longer meets the State Medicaid nursing facility level of care requirements and is not deemed eligible, the participant must be disenrolled.

Before an involuntary disenrollment is effective, the State Administering Agency must review it and determine in a timely manner that the PACE organization has adequately documented acceptable grounds for disenrollment. Once it has been deemed appropriate to involuntarily disenroll the participant, the PACE organization must follow the disenrollment process as defined in 42 CFR § 460.166 and discussed in [section 4.4.2](#) of this manual.

NOTE: A PACE organization may have a waiver allowing for involuntary disenrollment for additional reasons such as, disruptive or threatening behavior by a family member or failure of Medicaid participants to pay share of cost.

[42 CFR § 460.164(a), (b), (d), and (e); 71 FR 71315 (Dec. 8, 2006)]

#### **4.4.3 Additional Written Evidence of Involuntary Disenrollment for Disruptive or Threatening Behavior**

In addition to the documentation of disenrollment discussed in [section 4.4.1](#), if a PACE organization proposed to involuntarily disenroll a participant who is disruptive or threatening, the PACE organization must document the following information in the participant's medical records:

- The reasons for proposing to disenroll the participant; and
- All efforts to remedy the situation.

[42 CFR § 460.164(c)]

#### **4.4.4 Role of State Administering Agency**

At least annually, the State Administering Agency must re-evaluate whether or not a participant needs the level of care required under the State Medicaid plan for coverage of nursing facility services by using the eligibility criteria specified in the program agreement and by reviewing the participant's medical record or plan of care.

The State may permanently waive the annual recertification requirement if it determines there is no reasonable expectation of improvement or significant change in the participant's condition because of the severity of a chronic condition or the degree of impairment of functional capacity (NOTE: State authorized waiver of annual recertification, which includes the reason for waiving the annual recertification requirement, must be documented in the medical record).

Furthermore, the State Administering Agency may deem a participant who no longer meets the State Medicaid nursing facility level of care requirements to continue to be eligible for the PACE program if, in the absence of continued coverage under the program, the State Administering Agency determines the participant reasonably would be expected to meet the nursing facility level of care requirement in the next six months.

The State Administering Agency, must establish the criteria to use in making the determination of "deemed continued eligibility" and the criteria used to make the determination of continued eligibility must be specified in the program agreement. These criteria must be applied in reviewing the participant's medical record and plan of care. The State Administering Agency, in consultation with the PACE organization, may make a determination of deemed continued eligibility based on review of the participant's medical record and plan of care.

Finally, the State Administering Agency is responsible for reviewing medical record documentation and information about the involuntary disenrollment from a PACE

organization that plans to involuntarily disenroll a participant. As discussed above, in doing so, the State Administering Agency is required to determine in a timely manner that the PACE organization has adequately documented acceptable grounds for disenrollment.

[42 CFR § 460.160(b)]

## **4.5 Reinstatement in other Medicare and Medicaid Programs**

### **4.5.1 General Requirements**

To facilitate a participant's reinstatement in other Medicare and Medicaid programs after disenrollment, the PACE organization must do the following:

- Make appropriate referrals and ensure medical records are made available to new providers in a timely manner.
- Work with CMS and the State Administering Agency to reinstate the participant in other Medicare and Medicaid programs for which the participant is eligible.

[42 CFR § 460.168; §§ 1894(a)(2)(C) and 1934(a)(2)(C) of the Act]

### **4.5.2 Access to MA and Medigap Coverage following Disenrollment**

Individuals who disenroll from PACE have a Special Election Period for up to 2 months after the effective date of PACE disenrollment to elect an MA plan. If the individual decides to return to original Medicare, the individual may purchase a Medigap (Medicare supplemental) policy that is offered in their state within 63 days of the last date of coverage. Under a Guaranteed Issue Period, the issuer of a Medicare Supplemental Policy may not deny or condition the issuance or effectiveness of the policy; may not discriminate in the pricing of such policy, because of health status, claims experience, receipt of health care, or medical condition, and, may not impose an exclusion of benefits based on a preexisting condition. The agent or insurer may request evidence of the date of disenrollment along with the application for the policy. The effective date would be dependent upon the situation.

[42 CFR § 422.62(b)(4) and 71 FR 71246 (Dec. 8, 2006)]

### **4.5.3 Enrollment/Disenrollment of Hospitalized Beneficiaries**

The PACE organization must provide for the prompt transfer of copies of appropriate medical record information between treatment facilities to ensure continuity of care whenever a participant is temporarily or permanently transferred to another facility. Examples of appropriate medical record information include, but are not limited to:

- The reason for the transfer;

- The name and number of the attending physician;
- Participant's demographics;
- Active diagnoses and treatment plan including current medications and activities of daily living status;
- Special dietary considerations, etc.

It is essential that the medical history and plan of care follow the participant. This requirement is intended to ensure communication between providers.

More information regarding medical records documentation can be found in Chapter 12 of this manual.

[71 FR 71326 (Dec. 8, 2006)]

#### **4.6 Reinstatement in PACE**

A previously disenrolled participant may be reinstated in the PACE program. CMS did not adopt the protocol provision limiting a participant to a one-time-only reinstatement following a voluntary disenrollment because frail elderly individuals may experience living arrangement changes that take them in and out of a PACE organization's service area that may result in unavoidable disenrollments. If the reason for disenrollment is failure to pay the premium and the participant pays the premium before the effective date of disenrollment, the participant is reinstated in the PACE program with no break in coverage.

[42 CFR § 460.170]

## Chapter 5 - PACE Participant Rights and Restraint Policies

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### Table of Contents

<a href="#"><u>5.1 Participant Bill of Rights</u></a>	44
<a href="#"><u>5.2 Specific Rights to which a Participant is Entitled</u></a>	44
<a href="#"><u>5.2.1 Right #1 - Respect and Nondiscrimination</u></a>	44
<a href="#"><u>5.2.2 Right #2 - Information Disclosure</u></a>	45
<a href="#"><u>5.2.3 Right #3 - Choice of Providers</u></a>	46
<a href="#"><u>5.2.3.1 Primary Care Physician</u></a>	46
<a href="#"><u>5.2.3.2 Informing Female Participants</u></a>	47
<a href="#"><u>5.2.4 Right #4 - Access to Emergency Services</u></a>	47
<a href="#"><u>5.2.5 Right #5 - Participation in Treatment Decisions</u></a>	47
<a href="#"><u>5.2.6 Right #6 - Confidentiality of Health Information</u></a>	48
<a href="#"><u>5.2.7 Right #7 - Complaints and Appeals</u></a>	48
<a href="#"><u>5.3 Restraints</u></a>	49

## **5.1 Participant Bill of Rights**

The PACE organization is required to have a written participant Bill of Rights designed to protect and promote the rights of each participant. Those rights include, at a minimum, those specified in 42 CFR § 460.112.

The PACE organization must inform a participant upon enrollment, in writing, of his or her rights and responsibilities, and all rules and regulations governing participation. This should include:

- **Written policies:** A PACE organization must have written policies and implement procedures to ensure that the participant, his or her representative, if any, and staff understand these rights;
- **Explanation of rights:** The PACE organization must fully explain the rights to the participant and his or her representative, if any, at the time of enrollment in a manner understood by the participant;
  - The participants rights must be available in writing in English and in any other principal languages of the community;
  - The participant rights must be displayed in a prominent place within the PACE center.

The PACE organization must protect and provide for the exercise of the participant's rights. The PACE organization must have established documented procedures to respond to and rectify a violation of a participant's rights. A template for the Bill of Rights may be obtained from the following link <http://www.cms.hhs.gov/PACE/Downloads/participantrights.pdf>.

[42 CFR §§ 460.100, 460.116, and 460.188]

## **5.2 Specific Rights to which a Participant is Entitled**

### **5.2.1 Right #1 - Respect and Nondiscrimination**

Each participant has the right to considerate, respectful care from all PACE employees and contractors at all times and under all circumstances. Each participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental or physical disability, or source of payment.

Specifically, each PACE participant has the right to the following:

- To receive comprehensive health care in a safe and clean environment and in an accessible manner;
- To be treated with dignity and respect, be afforded privacy and confidentiality in all aspects of care, and to be provided humane care;
- Not to be required to perform services for the PACE organization;
- To have reasonable access to a telephone;
- To be free from harm, including physical or mental abuse, neglect, corporal punishment, involuntary seclusion, excessive medication, and any physical or chemical restraint imposed for purposes of discipline or convenience and not required to treat the participant's medical symptoms;
- To be encouraged and assisted to exercise rights as a participant, including the Medicare and Medicaid appeals processes as well as civil and other legal rights;
- To be encouraged and assisted to recommend changes in policies and services to PACE staff.

[42 CFR § 460.112(a)]

### **5.2.2 Right #2 - Information Disclosure**

Each PACE participant (or the designated representative of the participant) has the right to receive accurate, easily understood information and to receive assistance in making informed health care decisions.

Specifically, each participant has the following rights:

- To be fully informed of the services available from the PACE organization, including identification of all services that are delivered through contracts, rather than furnished directly by the PACE organization at the following times:
  - o Before enrollment;
  - o At enrollment; and
  - o At the time a participant's needs necessitate the disclosure and delivery of such information in order to allow the participant to make an informed choice;

- To have the enrollment agreement, described in 42 CFR §460.154, fully explained in a manner understood by the participant;
- To examine, or upon reasonable request, to be assisted to examine the results of the most recent review of the PACE organization conducted by CMS or the State Administering Agency and any plan of correction in effect.

[42 CFR § 460.112(b)]

### **5.2.3 Right #3 - Choice of Providers**

Each participant has the right to a choice of health care providers, within the PACE organization’s network, that is sufficient to ensure access to appropriate high-quality health care.

Specifically, each participant has the right to the following:

- To choose his or her primary care physician and specialists from within the PACE network;
- To disenroll from the program at any time;
- To request that a qualified specialist for women’s health services provide routine or preventive women’s health services. The PACE organization must:
  - o Provide access to all specialties within its network and explain to participants that they are required to receive all services through the PACE organization;
  - o Give participants the choice of providers as well as communicate the right of female participants to choose a qualified specialist in woman’s health;
  - o Contract when possible with more than one provider of gynecological services.

[42 CFR § 460.112(c); 71 FR 71291 (Dec. 8, 2006)]

#### **5.2.3.1 Primary Care Physician**

A Primary Care Physician (PCP) is qualified to perform primary care including basic Gynecological (GYN) services, but the PCP is not a “qualified specialist for women’s health services.” Although female participants may choose their PCP for basic GYN services, if a participant requests a GYN specialist or the participant requires more complex GYN services, the participant must be provided a GYN specialist and, when possible, be provided a choice of GYN specialists.

[71 FR 71291 (Dec. 8, 2006)]

### **5.2.3.2 Informing Female Participants**

The Interdisciplinary Team (IDT) physician or alternative IDT member identified in the organization's care planning policy should inform female participants that they are entitled to choose a qualified specialist for women's health services to provide routine or preventive women's health services from the PACE organization's network. In some PACE organizations, the physician makes this notification during intake, the enrollment process, or at the initial physician assessment. If notification has not been made prior to development of the care plan, 42 CFR § 460.104(b) requires the IDT team to make this notification during the care plan development or when the proposed care plan is subsequently presented to the participant and/or care giver for discussion, revision, and incorporation of the participant's preferences.

[42 CFR § 460.104(b); 71 FR 71296 (Dec. 8, 2006)]

### **5.2.4 Right #4 - Access to Emergency Services**

Each participant has the right to access emergency health care services when and where the need arises without prior authorization by the PACE IDT.

[42 CFR § 460.112(d)]

### **5.2.5 Right #5 - Participation in Treatment Decisions**

Each participant has the right to participate fully in all decisions related to his or her treatment. A participant who is unable to participate fully in treatment decisions has the right to designate a representative.

Specifically, each participant has the right:

- To have all treatment options explained in a culturally competent manner and to make health care decisions, including the right to refuse treatment, and be informed of the consequences of the decisions;
- To have the PACE organization explain advance directives and to establish them, if the participant so desires, in accordance with 42 CFR §§ 489.100 and 489.102;
- To be fully informed of his or her health and functional status by the interdisciplinary team;
- To participate in the development and implementation of the plan of care;

- To request a reassessment by the interdisciplinary team;
- To be given reasonable advance notice, in writing, of any transfer to another treatment setting and the justification for the transfer (that is, due to medical reasons or for the participant's welfare, or that of other participants). The PACE organization must document the justification in the participant's medical record.

[42 CFR § 460.112(e)]

### **5.2.6 Right #6 - Confidentiality of Health Information**

Each participant has the right to communicate with health care providers in confidence and to have the confidentiality of his or her individually identifiable health care and other information protected. Each participant also has the right to review and copy his or her own medical records and request amendments to those records.

Specifically, each participant has the following rights:

- To be assured of confidential treatment of all information contained in the health record, including information contained in an automated data bank;
- To be assured that his or her written consent will be obtained for the release of information to persons not otherwise authorized under law to receive it;
- To provide written consent that limits the degree of information and the persons to whom information may be given.

[42 CFR § 460.112(f)]

### **5.2.7 Right #7 - Complaints and Appeals**

Each participant has the right to a fair and efficient process for resolving differences with the PACE organization, including a rigorous system for internal review by the organization and an independent system of external review.

Specifically, each participant has the following rights:

- To be encouraged and assisted to voice complaints to PACE staff and outside representatives of his or her choice, free of any restraint, interference, coercion, discrimination, or reprisal by the PACE staff;
- To appeal any treatment decision of the PACE organization, its employees, or contractors through the process described in 42 CFR § 460.122.

### 5.3 Restraints

The use of restraints must be based on the assessed needs of the participant, be monitored and reassessed appropriately, and be ordered for a defined and limited period of time. The least restrictive and most effective method available must be utilized and it must conform to the participant's plan of care. Restraints may only be used as a last resort and must be removed or ended at the earliest possible time. Restraints of any kind should never be used as a preferred approach to care and PACE organizations are expected to ensure that their programs are "restraint free" to the greatest extent possible.

The term restraint includes physical or chemical restrains. A physical restraint as any manual method or physical or mechanical device, materials, or equipment attached or adjacent to the participant's body that he or she cannot easily remove and that restricts freedom of movement or normal access to one's body. A chemical restraint as a medication used to control behavior or to restrict the participant's freedom of movement, and that is not a standard treatment for the participant's medical or psychiatric condition.

If the IDT determines that a restraint is needed to ensure the participant's physical safety or the safety of others, the use must meet the following conditions:

- Be imposed for a defined, limited period of time, based upon the assessed needs of the participant;
- Be imposed in accordance with safe and appropriate restraining techniques;
- Be imposed only when other less restrictive measures have been found to be ineffective to protect the participant or other from harm;
- and
- Be removed or ended at the earliest possible time.

A PACE organization must have policies and procedures regarding constraints that:

- Define physical and chemical restraints as described above;
- Include the conditions on use described above;
- Describe how personnel will continually assess, monitor and reevaluate (specify time intervals) the participant's condition while in restraints.

[42 CFR § 460.114; 71 FR 71294 (Dec. 8, 2006)]

## Chapter 6 - PACE Services

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### Table of Contents

<a href="#"><u>6.1 Basic Rule</u></a>	51
<a href="#"><u>6.2 No Co-payments/Deductibles/ Fee-for-Service Limits on Medicare Services</u></a>	51
<a href="#"><u>6.3 Emergency Care</u></a>	52
<a href="#"><u>6.4 Urgently Needed and Post Stabilization Care</u></a>	52
<a href="#"><u>6.5 Service Delivery</u></a>	53
<a href="#"><u>6.5.1 Primary Care</u></a>	54
<a href="#"><u>6.5.2 Meal Requirements</u></a>	55
<a href="#"><u>6.5.3 Sanitary Conditions</u></a>	55
<a href="#"><u>6.5.4 Transportation Services</u></a>	56
<a href="#"><u>6.5.4.1 Safety, Accessibility, and Equipment</u></a>	56
<a href="#"><u>6.5.4.2 Maintenance of Vehicles</u></a>	56
<a href="#"><u>6.5.4.3 Communication with PACE Center</u></a>	56
<a href="#"><u>6.5.4.4 Training</u></a>	57
<a href="#"><u>6.6 Required Services for Medicare Participants</u></a>	57
<a href="#"><u>6.7 Excluded Services</u></a>	57

## **6.1 Basic Rule**

The PACE benefit package is required to include for all participants, regardless of source of payment, all Medicare covered services, all Medicaid covered services as specified in the State's approved Medicaid plan, and any other services determined necessary by the IDT to meet the participant's needs and which improve or maintain the participant's overall health status. IDT Assessment is the foundation for provision of participant-specific, appropriate services. See Chapter 8 for composition and description of the scope of IDT responsibilities.

The PACE organization must establish and implement a written plan to provide care that meets the needs of its participants across all care settings on a 24-hour basis each day of the year. The PACE organization must furnish comprehensive medical, health, and social services that integrate acute and long-term care. These services must be furnished at least in the PACE center, the participant's home, and inpatient facilities such as acute and long term care hospitals and nursing/rehabilitation facilities. The PACE organization must not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental or physical disability, or source of payment.

[42 CFR §§ 460.92, 460.98(a) and (b)]

## **6.2 No Co-payments/Deductibles/ Fee-for-Service Limits on Medicare or Medicaid Services**

If a Medicare beneficiary or Medicaid recipient chooses to enroll in a PACE program, Medicare and Medicaid benefit limitations and conditions relating to amount, duration, scope of services, deductibles, copayments, coinsurance, or other cost-sharing do not apply. The amount, duration and scope of services provided to PACE participants are participant-specific and are specified by the IDT in the plan of care. The scope of benefits under PACE includes any other item or service determined necessary by the IDT to improve and maintain the participant's overall health status.

Under sections 1894(a) and 1934(a) of the Act, PACE participants must receive Medicare and Medicaid benefits solely through the PACE organization. PACE organizations are required to provide enrollees with all medically necessary services, including drugs, without any limitation or condition as to the amount, duration, or scope. The PACE benefit includes all outpatient prescription drugs, as well as over-the-counter medications indicated by the participant's care plan. PACE programs cannot charge deductibles, copayments, coinsurance or other cost-sharing for medications.

The PACE organization may contract with other providers for specialty medical or other services to meet participant needs. The PACE organization must maintain primary responsibility and accountability for participant care in all settings and for all provided services. Please refer to Chapter 9 for a description of PACE organization oversight requirements for all services.

[42 CFR § 460.90; 71 FR 71248 and 71280 (Dec. 8, 2006)]

### **6.3 Emergency Care**

Emergency care is appropriate when services are needed immediately because of an injury or sudden illness and the time required to reach the PACE organization or one of its contract providers, would cause risk of permanent damage to the participant's health. Emergency services include inpatient and outpatient services that meet the following requirements:

- Are furnished by a qualified emergency services provider, other than the PACE organization or one of its contract providers, either in or out of the PACE organization's service area;
- Are needed to evaluate or stabilize an emergency medical condition. An emergency medical condition means a condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in serious jeopardy to health of the participant, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.

The organization must ensure that the participant or caregiver, or both, understand when and how to access emergency services and that no prior authorization is needed.

A PACE organization must establish and maintain a written plan to handle emergency care. The plan must ensure that CMS, the State, and PACE participants are held harmless if the PACE organization does not pay for emergency services. The written plan also must provide for an on-call provider to be available 24-hours per day to address participant questions about emergency services and respond to requests for authorization of urgently needed out-of-network services and post stabilization care services following emergency services.

[42 CFR § 460.100(a), (b), (c), (d), and (e)(1)]

### **6.4 Urgently Needed and Post Stabilization Care**

Urgent care means the care provided to a PACE participant who is out of the PACE services area, and who believes their illness or injury is too severe to postpone treatment until they return to the service area, but their life or functioning is not in severe jeopardy. Post-stabilization care means services provided subsequent to an emergency that a treating physician views as medically necessary after an emergency medical condition has been stabilized. They are not emergency services, which PACE organizations are obligated to cover. Rather, they are non-emergency services that the PACE organization should approve before they are provided outside of the service area.

The PACE organization must establish and maintain a written plan which provides for coverage of urgently needed out-of-network and post-stabilization care services when either of the following conditions is met:

- The services are preapproved by the PACE organization; or
- The services are not preapproved by the PACE organization because the PACE organization did not respond to a request for approval within one hour after being contacted or cannot be contacted for approval.

An on-call provider must be available 24-hours per day to address participant questions about emergency services and respond to requests for authorization of urgently needed out-of-network services and post stabilization care services following emergency services.

Periodic education of participants is necessary to ensure they and their caretakers can distinguish between urgent and emergent care needs, and to emphasize that PACE authorization is never required before seeking emergency care. The PACE organization needs to educate its participants in the difference between emergency care (where prior authorization is not required) , and urgent care (where prior authorization is appropriate). Participants need to understand when to request prior authorization and when to request urgent care.

[42 CFR § 460.100(e)(2) and (3); 71 FR 71284 and 71297 (Dec. 8, 2006)]

## **6.5 Service Delivery**

The PACE organization must operate at least one PACE center either in or contiguous to its designated service area with sufficient capacity for routine attendance by its participants.

The PACE organization must ensure accessible and adequate services to meet the needs of all its participants. When necessary, the organization must increase the number of centers, staff, and other PACE services.

If a PACE organization operates more than one center, each PACE center must offer the full range of services and have sufficient staff to meet the needs of participants.

The frequency of a participant's attendance at the center is determined by the IDT based on the needs and preferences of each participant.

**At a minimum the following services must be furnished by each PACE center:**

- Multidisciplinary assessment and treatment planning;

- Primary care services including physician and nursing services;
- Social work services;
- Restorative therapies, including physical therapy, occupational therapy and speech therapy;
- Personal care and supportive services;
- Nutritional counseling;
- Recreational therapy;
- Transportation;
- Meals.

These services and others are described in detail below.

[42 CFR § 460.98(c), (d), and (e)]

### **6.5.1 Primary Care** (including physician and nursing services)

Primary medical care must be furnished to a participant by a PACE primary care physician. Each primary care physician is responsible for managing a participant's medical situation and for overseeing a participant's use of medical specialists and inpatient care. Other primary care services provided by physicians and/or nurses include:

- Medical and medication history, assessment, diagnosis, treatment, education and team care planning by a primary care physician;
- Management of a participant's medical condition;
- Referral to and oversight of specialists;
- Oversight of inpatient care;
- Informing female participants about their right to select a qualified specialist for women's health services;

[42 CFR § 460.102(c)]

## **6.5.2 Meal Requirements**

Except when a participant has a problem and must receive substitute foods or nutritional supplements or needs nutrition support (as discussed below) the PACE organization must ensure, through the assessment and care planning process that each participant receives nourishing, palatable, well-balanced meals that meet the participant's daily nutritional/medical and special dietary needs. Meals should be procured, prepared and provided by appropriately trained/certified/experienced food service staff (i.e. qualified by training/certification in food safety and sanitation). Each meal must meet the following requirements:

- Be prepared by methods that conserve nutritive value, flavor, and appearance;
- Be prepared in a form designed to meet individual needs; and
- Be prepared and served at the proper temperature.

The PACE organization must provide substitute foods or nutrition supplements that meet the daily nutritional and special dietary needs of any participant who has any of the following problems:

- Refuses the food served;
- Cannot tolerate the food served;
- Does not consume adequate calories and nutrients appropriate in meeting the individual's estimated nutritional needs determined at the initial and interim assessments.

The PACE organization must provide nutrition support to meet the daily nutritional needs of a participant, if indicated by his or her medical condition or diagnosis. Nutrition support consists of tube feedings, total parenteral nutrition, or peripheral parenteral nutrition.

[42 CFR § 460.78(a)]

## **6.5.3 Sanitary Conditions**

The PACE organization must do the following:

- Procure foods (including nutritional supplements and nutrition support items) from sources approved or considered satisfactory, by Federal, State, Tribal, or local authorities with jurisdiction over the service area of the organization;

- Store, prepare, distribute, and serve foods (including nutritional supplements and nutrition support items) under sanitary/safe conditions;
- Dispose of garbage and refuse properly.

Should Nutrition Services be contracted outside of the PACE organization, the contractor must be able to show appropriate/current state and/or local certification demonstrating adequate food preparation facilities, transportation and have staff with training and experience able to provide safe, nourishing, palatable, well-balanced meals that meet national standards for the population being served.

[42 CFR §§ 460.70 and 460.78(b)]

#### **6.5.4 Transportation Services**

Transportation must be provided as indicated in a participant's plan of care. As part of the IDT process, PACE organization staff (employees and contractors) must communicate relevant changes in a participant's care plan to transportation personnel. The IDT must have a process in place to get input from the transportation personnel regarding status and changes noted in participant condition.

[42 CFR §§ 460.76(e), 460.102(e)]

##### **6.5.4.1 Safety, Accessibility, and Equipment**

A PACE organization's transportation services must be safe, accessible, and equipped to meet the needs of the participant population.

[42 CFR § 460.76(a)]

##### **6.5.4.2 Maintenance of Vehicles**

If the PACE organization owns, rents, or leases transportation vehicles, it must maintain these vehicles in accordance with the manufacturer's recommendations.

If a contractor provides transportation services, the PACE organization must ensure that the vehicles are maintained in accordance with the manufacturer's recommendations.

[42 CFR § 460.76(b)]

##### **6.5.4.3 Communication with PACE Center**

The PACE organization must ensure that transportation vehicles are equipped to communicate with the PACE center.

#### **6.5.4.4 Training**

The PACE organization must train all transportation personnel (employees and contractors) in the following:

- Managing the special needs of participants;
- How to, and types of issues to communicate to the PACE center staff about participants;
- Handling emergency situations;
- Transportation workers are considered direct care workers. All health requirements and background checks must be assured by human resources or contractor oversight.

[42 CFR §§ 460.64, 460.76(d), and 460.102(e)]

#### **6.6 Required Services for Medicare Participants**

The PACE benefit package for Medicare participants must include, in addition to the service required by § 460.92, the scope of hospital insurance benefits described in 42 CFR part 409 and the scope of supplemental medical insurance benefits described in 42 CFR part 410. In addition some requirements of title XVIII of the Act are waived and do not apply to services under the PACE program which include:

- The provisions of subpart F of part 409 of 42 CFR that limit coverage of institutional services;
- The provisions of subparts G and H of 42 CFR part 409 and parts 412 through 414 that relate to rules for payment for benefits;
- The provisions of subparts D and E of 42 CFR part 409 that limit coverage of extended care services or home health services;
- The provisions of subpart D of 42 CFR part 409 that impose a 3-day prior hospitalization requirement for coverage of extended care services; and
- The provisions of 42 CFR 411.15(g) and (k) that may prevent payment for PACE program services to individuals enrolled in the PACE program.

[42 CFR § 460.94]

#### **6.7 Excluded Services**

The services that are excluded from coverage under the PACE program are as follows:

- Any service that is not authorized by the IDT, even if it is listed as a required service, unless it is an emergency service;
- Services rendered in a non-emergency setting or for a non-emergency reason without authorization;
- Prescription and over-the-counter drugs not prescribed by the PACE provider physician;
- For services in inpatient facilities, private room and private duty nursing services, (unless medically necessary) and non-medical items for personal convenience such as telephone charges, radio or television rental, (unless specifically authorized by the IDT as part of a participant's plan of care);
- Cosmetic surgery, which does not include surgery required for improved functioning of a malformed part of the body resulting from an accidental injury or for reconstruction following mastectomy;
- Experimental medical, surgical or other health procedures.

PACE will not cover services rendered outside the United States, except as may be permitted in accordance with 42 CFR § 424.122 regarding conditions for payment for emergency inpatient hospital services and 42 CFR § 424.124 regarding conditions for payment for physician services and ambulance services or as may be permitted under the State's approved Medicaid Plan. There are limited exceptions to this rule. For example, a State that borders another country might include some Medicaid coverage across the border, and Medicare covers some emergency hospital, ambulance, and physician services outside the United States. (As defined in 42 CFR § 400.200, the United States includes the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands).

[42 CFR § 460.96; 71 FR 71282 (Dec. 8, 2006)]

## Chapter 7 – PACE Service Delivery Settings

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### Table of Contents

<a href="#"><u>7.1 Introduction</u></a>	60
<a href="#"><u>7.2 PACE Center</u></a>	60
<a href="#"><u>7.2.1 Physical Environment</u></a>	60
<a href="#"><u>7.2.2 Frequency of Attendance at the PACE Center</u></a>	60
<a href="#"><u>7.2.3 Equipment</u></a>	61
<a href="#"><u>7.2.3.1 Equipment Maintenance</u></a>	61
<a href="#"><u>7.2.4 Emergency Equipment</u></a>	61
<a href="#"><u>7.2.5 Fire Safety</u></a>	62
<a href="#"><u>7.2.6 Emergency and Disaster Preparedness</u></a>	63
<a href="#"><u>7.2.7 Participant Safety and Comfort</u></a>	64
<a href="#"><u>7.2.8 Infection Control</u></a>	65
<a href="#"><u>7.3 Alternative Care Setting</u></a>	66
<a href="#"><u>7.5 Institutional Settings</u></a>	68

## **7.1 Introduction**

The PACE organization will have a written plan and procedure specifying how the organization meets the individualized needs of each participant in all care settings 24-hours a day, every day of the year.

## **7.2 PACE Center**

### **7.2.1 Physical Environment**

The PACE organization's physical environment must be designed, constructed, equipped and maintained to provide for the physical safety of participants, personnel and caregivers, and visitors. The PACE organization is required to ensure a safe, sanitary, functional, accessible and comfortable environment for the delivery of services that protects the dignity and privacy of the participant. The PACE center must include:

- Suitable space and equipment to provide primary medical care and suitable space for treatment, restorative therapies, therapeutic recreation, socialization, dining (food and nutritional supplement storage, meal preparation and serving), personal care, participant laundry, etc.;
- Suitable meeting space for personnel to conduct team meetings and for participants/caregivers, and visitors;
- Protecting the participant's privacy and dignity during the delivery of services.

The PACE organization must provide evidence that there are life safety code inspection results of fire marshal inspections, public health inspections, and other required state agency inspections.

The PACE organization must provide evidence of a federal Clinical Laboratory Improvement Amendment (CLIA) exemption if the center is performing waived laboratory services on site or in the home, e.g. glucose meter testing, urine testing, fecal occult blood testing, blood testing, cholesterol screening or hemoglobin or hematocrit testing.

In addition, the PACE organization's must meet all applicable Federal, State, and local laws and regulations, which include the Americans with Disabilities Act and section 504 of the Rehabilitation Act.

[42 CFR § 460.72(a)(1) and (2), and (b)(1) and the PACE State Readiness Review Guide]

### **7.2.2 Frequency of Attendance at the PACE Center**

The PACE center provides a point of service where the primary care clinic is located, where services are provided, and socialization occurs with staff that is consistent and familiar. Attendance at the center is an important aspect of the PACE model, which helps to differentiate it from home health care or institutional care.

The frequency of a participant's attendance at the center is determined by the IDT based on the needs and preferences of each participant. The PACE organization is expected to maintain a written plan specifying the criteria used to determine the number of hours and days a participant attends the center. These criteria should take into account the participant's medical condition, behavioral, psychosocial and personnel care needs, caregiver support and preferences.

[42 CFR §§ 460.98(e) and 460.106]

### **7.2.3 Equipment**

#### **7.2.3.1 Equipment Maintenance**

A PACE organization must perform the manufacturer's recommended maintenance on all equipment as indicated in the manufacturer's written recommendations. This maintenance may be performed by PACE staff or contracted entities and in compliance with the contract.

A PACE organization must establish, implement and maintain a written plan to ensure that all equipment is maintained in accordance with the manufacturer's recommendations.

[42 CFR § 460.72(a)(3)]

### **7.2.4 Emergency Equipment**

The PACE organization is required to have trained personnel, drugs, and emergency equipment immediately available at every PACE center at all times to adequately support participants until Emergency Medical Services (EMS) responds to the PACE center. Each PACE center is required to have at least one staff member who has been trained in cardio-pulmonary resuscitation (CPR) and will be in attendance during the hours that participants are in attendance.

The minimum emergency equipment that must be on the premises and immediately available includes: automated external defibrillator (AED), portable oxygen, airways, suction, and emergency drugs.

The PACE organization must have a written plan and procedure for handling emergency situations that may arise including, but not limited, to cardiac arrest, choking and seizure activity.

In addition, the PACE center must have a documented plan to obtain Emergency Medical Services from sources outside the PACE center when needed. At least annually, a PACE organization must test, evaluate, and document the effectiveness of its emergency and disaster plans to ensure and maintain appropriate responses to the situations and needs that may arise from both medical and nonmedical emergencies.

[42 CFR § 460.72(c); 71 FR 71275 (Dec. 8, 2006)]

### **7.2.5 Fire Safety**

A PACE center must meet the applicable provisions of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association that apply to the type of setting in which the center is located. Copies of the code may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269 (<http://www.nfpa.org/index.asp?cookie%5Ftest=1>). CMS will publish any changes in the Federal Register to announce any changes in this edition.

The LSC provisions do not apply in a state in which CMS determines that a fire and safety code imposed by state law adequately protects participants and staff and (2) CMS may waive specific provisions of the LSC that, if rigidly applied, would result in unreasonable hardship on the center, but only if the waiver does not adversely affect the health and safety of participants and staff.

Although there is specific waiver authority under the PACE statute, CMS PACE staff do not have the authority to approve waivers of the LSC. Rather, CMS staff responsible for Life Safety Code compliance would have to approve LSC waivers. Since PACE centers are often licensed as adult day health centers or clinics, they are not among the types of Medicare providers that CMS typically surveys for compliance with the LSC. As a result, CMS will accept State licensure requirements related to fire and safety as meeting the LSC.

The SAA assures that LSC requirements are met for facilities in which the PACE organization furnishes services to PACE participants in accordance with 42 CFR §460.72(b).

CMS recognizes that the responsibility for certifying compliance with state licensure laws concerning fire safety may not be a direct function of the State Administering Agency. For example, the clinical and building code expertise associated with this function may lend itself to a separate branch or State office.

However, CMS depends on the State Administering Agency as the single point of contact on all State-related requirements regardless of whether the functions are housed directly within the State Administering Agency. In the case of fire and safety codes imposed by State law, the State Administering Agency may find it necessary to secure appropriate documentation from the entity with jurisdiction over these areas.

Beginning March 13, 2006 a PACE center must be in compliance with the 2000 LSC Edition, Chapter 9.2.9, [42 CFR § 460.72(b)(3)] which states that Emergency Lighting must provide illumination for at least a 90-minute duration.

Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a PACE center may install alcohol-based hand rub dispensers if:

- The use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub facilities in health care facilities;
- The dispensers are installed in such a manner that minimizes leaks and spills that could lead to falls;
- The dispensers are installed in a manner that adequately protects against inappropriate access;
- The dispensers are installed in accordance with Chapter 18.3.2.7 or Chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by National Fire Protection Association Temporary Interim Amendment; and
- The dispensers are maintained in accordance with dispenser manufacturer guidelines.

[42 CFR § 460.72(b); 71 FR 71275 (Dec. 8, 2006) and the PACE Program Agreement]

### **7.2.6 Emergency and Disaster Preparedness**

Emergencies include, but are not limited to the following:

- Fire;
- Equipment, water or power failure;
- Care-related emergencies;
- Natural disasters likely to occur in the organization's geographic area (An organization is not required to develop emergency plans for disasters that typically do not affect its geographic location).

The PACE organization must establish, implement and maintain documented procedures to manage medical and non-medical emergencies and disasters that are likely to threaten the health and safety of participants, staff or the public. The Disaster Plan must address the organization's arrangements for emergency food, nutritional supplements and potable water supplies.

A PACE organization must provide appropriate training and periodic orientation to all employees and contracted staff and participants to ensure that all staff demonstrate a knowledge of emergency procedures, including information on what to do, where to go, and whom to contact in case of emergency.

At least annually, a PACE organization must actually test and evaluate the effectiveness of its emergency and disaster plans. Documentation must be maintained for all fire and disaster plan drills conducted by the PACE organization, along with records of all training conducted for direct and contracted staff.

[42 CFR § 460.72(c)]

### **7.2.7 Participant Safety and Comfort**

The PACE organization's physical environment must be designed, constructed, equipped and maintained to provide for the physical safety of participants, personnel caregivers, and visitors. The PACE organization is responsible for maintaining a safe, sanitary, functional, accessible and comfortable environment for the delivery of services that meet the physical needs, and protects the dignity and privacy of the participant.

In order for the environment to be considered safe and comfortable the center, along with alternative care settings, the facility must:

- Be accessible for the wheel chair bound person;
- Have the entry and hallways wide enough to accommodate a stretcher;
- Any handrails affixed to corridors should be intact and free of splinters;
- Have a functioning call system in all bathing areas and participant toilets;
- Have water temperatures safe and comfortable;
- Have well ventilated participant areas;
- Keep housekeeping compounds and other chemicals stored to prevent participant or visitor access;
- Be as free of accident hazards as possible;
- Be clean and pest free; and
- Be free of objectionable odors.

The PACE organization is expected to have a plan and procedure to address building security while open and after hours, including preventing participants from wandering offsite and a process for identifying participants and visitors.

[42 CFR § 460.72(a)(1) and the State Readiness Review document]

### **7.2.8 Infection Control**

The PACE organization must establish, develop, implement, and maintain a documented infection control plan that ensures a safe and sanitary environment and prevents and controls the transmission of disease and infection. An infection control plan must include, but is not limited to: (1) procedures to prevent, identify, investigate, and control infections in every PACE center and in each participant's place of residence; (2) procedures to record any incidents of infection; and (3) procedures to analyze the incidents of infection to identify trends and develop corrective actions related to the reduction of future incidents. PACE organizations must follow accepted policies and standard procedures with respect to infection control, including at the least the standard precautions developed by the Center for Disease Control and Prevention (CDC).

PACE organizations are expected establish written policies and procedures for the investigation, control, and prevention of infections including:

- An OSHA Exposure Control Plan which includes the Universal Precautions and Bloodborne Pathogen exposure procedures for staff;
- Vaccinating participants and staff against diseases of particular concern for the PACE participant and the center's geographic location, i.e. influenza and pneumonia;
- Initial and ongoing health screening and vaccinations for staff and participants in accordance with OSHA regulations (staff) and CDC guidelines for tuberculosis, Hepatitis B and other communicable diseases;
- Written plans and procedures for the investigation, evaluation, resolution, and reporting of all incidences of staff and participant infection;
- Written plans and procedures for maintaining records of staff and participant infections to include post-exposure evaluation, training records, and participant and staff surveillance reports. Written plans and procedures for reporting required communicable diseases to the appropriate state and local officials;
- Plans and procedures for staff providing direct care to patients with infection(s);

- Provision of adequate facilities and supplies necessary for infection control to include:
  - Hand washing facilities and supplies;
  - Laundry facilities and supplies;
  - Isolation facilities and supplies;
- Written plans and procedures for addressing how laundry will be handled. If the service is contracted out, written agreements to comply with the requirements;
- Written plans and procedures for the ongoing monitoring of the contractual agreement provisions for laundry and waste disposal;
- Written plans and procedures for the appropriate handling and disposal of all waste products including blood and urine specimens for outside lab tests and other biohazardous wastes.

The CDC Guidelines for Environmental Infection Control in Health Care Facilities can be found at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm>. The OSHA Guidelines for the handling of laundry and labeling of bio-hazardous waste can be found at [http://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=STANDARDS&p\\_id=10051#1910.1030\(d\)\(4\)\(iv\)](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051#1910.1030(d)(4)(iv)). Check with the State Administering Agency for the Guidelines for Environmental Infection Control in Health Care Facilities established by the State in which the PACE organization resides.

### **7.3 Alternative Care Setting**

Alternative care settings are allowed when a limited number of services may be provided. An alternative care setting is a physical facility, other than the participant's place of residence, where PACE participants receive any of the required services. These settings are a compliment to the PACE organization and not an actual part of the PACE organization. For an example, an adult day center on the weekends for a blind participant.

All PACE organizations must notify CMS in writing (US mail or email) of any new arrangements being proposed whereby participants are transported from their place of residence to an alternative care setting. The arrangement minimally must describe what services will be offered, how the services will be provided, the location of the new setting, the staffing at the proposed new location, Interdisciplinary team members involved and participant (both written and oral) communication considerations.

The following is an outlined procedure for the PACE organization:

- The PACE organization will notify the CMS Central Office team leader prior to your organization opening or contracting with a provider to use an alternative care setting;
- The CMS Central Office team leader will contact the State Administering Agency to ascertain their knowledge of the new arrangement;
- The CMS Central Office team leader will schedule a conference call with your organization, the State Administering Agency and the CMS Regional Office to discuss details of the proposed arrangement;
- The CMS Central Office team leader will request additional written information from the PACE organization, if necessary, to ensure participants rights are upheld.

Additional information that may be requested:

- A listing of services offered at the alternative care setting;
- A description of the business relationship between the alternative care setting and the PACE organization;
- The location of the setting in relation to the approved service area;
- A description of staffing at the new setting;
- A description of transportation arrangements;
- A description of the interaction of interdisciplinary team members who oversee the care of participants attending the alternative care setting;
- PACE organization oversight of the alternative care setting;
- A description of how the building/space fire and safety codes meet the National Fire Protection Association 2000 guidelines;
- The proposed marketing strategy and material to be used to inform existing and new enrollees of the new setting.

CMS Central and Regional Offices and the State Administering Agency will review all additional information. If the alternative care setting does not meet the PACE center definition, no further action will be required of the three parties (CMS, State Administering Agency and the PACE organization). Ongoing monitoring reviews will confirm that arrangements are consistent with the PACE organization's proposed arrangement.

If, after reading the additional information, it has been determined that the new setting has met the regulatory definition of a PACE center, the PACE organization will be assisted in developing an expansion application. This application can be found at:

[www.cms.hhs.gov/PACE](http://www.cms.hhs.gov/PACE).

CMS Central and Regional Office will review the expansion application after the application has been approved by the State Administering Agency. If the expansion requires an onsite readiness review (in the case of a new proposed center), the State Administering Agency will complete the review. The completion of the readiness review is necessary prior to approval of the expansion application.

[71 FR 71283 (Dec. 8, 2006) and CMS Call Letter (June 23, 2004)]

#### **7.4 Institutional Settings**

Institutional settings include, but are not limited to, acute care hospitals, rehabilitation hospitals and distinct part rehabilitation units of acute care hospitals, psychiatric hospitals and distinct part psychiatric units of acute care hospitals, and critical access hospitals, nursing facilities and skilled nursing facilities. The PACE organization must contract only with institutional entities that meet all applicable Federal and State requirements as well as meet the Medicare or Medicaid participation requirements. There are provider specific Conditions of Participation for institutions that participate in the Medicare program. Therefore, all institutional contractors must be in compliance with their respective Conditions of Participation.

When a participant's care needs cannot be accommodated in the PACE center clinic and the organization extends its care options by contracting providers to deliver specialized services, the IDT does not "hand off" the participant's care; it expands the care team by collaborating with contracted specialists and placing participants in more appropriate healthcare settings to meet new needs. This concept is clearly supported by PACE regulations governing contracted services which require the PACE organization to maintain responsibility for the participant's care whether the care is delivered by the PACE organization or contractors. For example, when the PACE organization solicits services by a contractor or contracted facility, it must specify in the contract that the contractor furnishes only those services authorized by the PACE IDT and agrees to be accountable to the PACE organization [42 CFR § 460.70(d)(5)]. Or, when participants are admitted to an acute/long term/rehab facility or transferred temporarily, during that time away and upon return to program the Registered Dietician. is responsible in maintaining communications as to the management of any dietary care plan changes and alters the nutrition program accordingly to keep current with the member's health/medicinal/gastrointestinal changes.

PACE organizations cannot be reticent about exerting their contractual and regulatory authority to actively engage in the care of PACE participants placed in contracted facilities.

CMS expects the PACE organization to establish a good working relationship with the contracted facility staff.

[42 CFR § 460.70]

## Chapter 8 PACE IDT, Assessment & Care Planning

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### Table of Contents

<a href="#"><u>8.1 Introduction - Section 1 Interdisciplinary Team (IDT)</u></a>	72
<a href="#"><u>8.1.1 Interdisciplinary Team Composition</u></a>	72
<a href="#"><u>8.1.2 Basic Information for an Established IDT</u></a>	73
<a href="#"><u>8.1.3 Requirements for the IDT</u></a>	74
<a href="#"><u>8.2 Introduction- Section 2 Assessment</u></a>	74
<a href="#"><u>8.2.1 PACE Organization Responsibilities</u></a>	74
<a href="#"><u>8.2.2 Timing of Assessments</u></a>	76
<a href="#"><u>8.2.2.1 Pre Enrollment</u></a>	76
<a href="#"><u>8.2.2.2 Initial Assessment</u></a>	76
<a href="#"><u>8.2.2.3 Assessment of Multiple New Participants</u></a>	77
<a href="#"><u>8.2.3 Assessment Process</u></a>	77
<a href="#"><u>8.2.3.1 Initial Assessment</u></a>	77
<a href="#"><u>8.2.3.2 Semiannual Reassessments</u></a>	78
<a href="#"><u>8.2.3.3 Annual Reassessments</u></a>	79
<a href="#"><u>8.2.3.4 Periodic and Unscheduled Health Reassessments</u></a>	79
<a href="#"><u>8.2.3.5 Recommendations for the Assessment Process</u></a>	80
<a href="#"><u>8.2.3.6 Changes to Plan of Care and Documentation</u></a>	80
<a href="#"><u>8.3 Introduction Section 3 Care Planning</u></a>	81
<a href="#"><u>8.3.1 PACE Care Planning Overview</u></a>	81
<a href="#"><u>8.3.2 PACE Care Planning and the Interdisciplinary Team</u></a>	81

<a href="#"><u>8.3.3 Plan of Care Development</u></a>	81
<a href="#"><u>8.3.3.1 Single Plan of Care</u></a>	81
<a href="#"><u>8.3.3.2 Participant / Caregiver Involvement in Care Planning Process</u></a>	82
<a href="#"><u>8.3.3.3 Contents of the Plan of Care</u></a>	82
<a href="#"><u>8.3.3.4 Differentiating Progress Notes and Care Plan Contents</u></a>	83
<a href="#"><u>8.3.4 Monitoring Participant Health Status</u></a>	84
<a href="#"><u>8.3.5 Documentation of Plan of Care</u></a>	84
<a href="#"><u>8.3.6 Plan of Care Revision</u></a>	84
<a href="#"><u>8.3.7 Continuous Plan of Care Monitoring and Evaluation</u></a>	85

## **Section 1 - Interdisciplinary Team (IDT)**

### **8.1 Introduction**

The intent of this portion of the chapter is to clarify the regulatory requirements for the Interdisciplinary Team (IDT) as defined by the regulatory PACE Protocol. CMS developed a guidance to provide an in-depth description of PACE care planning that provides additional clarification regarding IDT requirements for the PACE program. Care Planning Guidance for PACE Organizations, September 1, 2010 is available at

[http://www.cms.gov/PACE/09\\_AdditionalResources.asp#TopOfPage](http://www.cms.gov/PACE/09_AdditionalResources.asp#TopOfPage).

#### **8.1.1 Interdisciplinary Team Composition**

The IDT is critical to the success of the PACE program. Each of the eleven (11) IDT roles must be fulfilled by specific individuals who are employed or contracted by the PACE organization. It is not recommended that one individual fill multiple IDT roles. For example, a single registered nurse must not simultaneously fill the role of IDT registered nurse, home care coordinator, and PACE center manager [42 CFR § 460.102].

The IDT is composed of, but not limited to, at least the following members:

- Primary Care Physician;
- Registered Nurse;
- Master's Level Social Worker;
- Physical Therapist;
- Occupational Therapist;
- Recreational Therapist or Activity Coordinator;
- Dietitian;
- PACE Center Manager;
- Home Care Coordinator;
- Personal Care Attendant or his or her representative;
- Driver or his or her representative.

The IDT members must be legally authorized (licensed, certified, registered) to practice in the State in which they provide services and possess the ability to actively participate as an effective member of the team in the development and monitoring of each participant's plan of care. The IDT members may be employed or contracted staff. However, if the PACE organization uses contracted IDT members, they must meet the same personnel requirements and perform the same responsibilities as employed IDT members. All members of the IDT must primarily serve PACE participants. PACE organizations may apply for a waiver to contract with community-based primary care physicians when the organization can demonstrate that extenuating circumstances warrant this arrangement. If CMS grants this waiver, and the community-based physicians are contracted as the IDT physician, they must provide all the additional services required in that role. See Chapter 9, PACE Organization Relationships with Health Care Providers, for further information.

[42 CFR §§ 460.64 and 460.102(b) and (d)(3); Section 903 of BIPA]

### **8.1.2 Basic Information for an Established IDT**

The PACE organization must establish, implement, and maintain documented internal procedures governing the exchange of information between team members, contractors, and participants and their caregivers consistent with the requirements for confidentiality in section 460.200(e). The IDT approach involves timely and effective communications, interactive problem-solving, and the exchange of information between team members, contractors, participants and their caregivers in order to create mutual goals for the participant, while maintaining participant confidentiality. See Chapter 12 Medical Records and Participant Information for further information. Each team member is responsible for informing the IDT of the medical, functional, and psychosocial condition of each participant in an ongoing manner. [42 CFR § 460.102(d)(2)(i)]

The following questions should be answered during the team meetings:

- What information is shared? And when?
- What is the interaction of the other team members?
- When there is an initial or periodic assessment:
  - Does the team consider a home assessment by the therapist if the participant has a functional disability or is compromised?
  - Does the team consider a plan of care for all of the diagnoses that effect the participant's health or well being?
  - Does the physician appear to be involved in the participant's care in other settings (inpatient or nursing facilities)?

- o Is there any contract staff providing care or services?
  - Do they attend the meetings; if not, how is their input obtained?

### **8.1.3 Requirements for the IDT**

PACE organizations must establish an IDT at each center to comprehensively assess and meet the individual needs of each participant and assign each participant to an IDT functioning at the PACE center that the participant attends. The IDT is responsible for the initial and periodic assessments, plan of care, and coordination of 24-hour care delivery. Each team member is responsible for: (1) regularly informing the IDT of the medical, functional, and psychosocial condition of each participant; (2) remaining alert to pertinent input from other team members, participants, and caregivers; and (3) documenting changes of a participant's condition in the participant's medical record consistent with documentation policies established by the medical director. Additionally, IDT members must serve primarily PACE participants.

As part of the initial assessment, eight of the eleven IDT members (Primary Care Physician, Registered Nurse, Master's Level Social Worker, Physical Therapist, Occupational Therapist, Home Care Coordinator, Dietitian, and Recreational Therapist or Activity Coordinator) evaluate the participant in person, at appropriate intervals and develop a discipline-specific assessment of the participant's health and social status. At the recommendation of individual team members, other professional disciplines (for example, Speech-Language Pathology, Dentistry, or Audiology) may be included in the comprehensive assessment process.

[42 CFR §§ 460.102(a) and (d) and 460.104(a); 71 FR 71288 (Dec. 8, 2006)]

## **Section 2 – Participant Assessment**

### **8.2 Introduction**

This portion of Chapter 8 focuses on Participant Assessment Requirements and providing additional guidance related to the participant assessments.

#### **8.2.1 PACE Organization Responsibilities**

The PACE organization must have a care management strategy to address the major health needs of the participant for the interim period between intake assessment, official enrollment, and initial comprehensive assessment leading to the development of the initial care plan. The interim care management strategy may be documented in the discipline-specific progress notes or other section of the medical record identified by the organization and documented in policy and procedures.

PACE organizations should have policies and procedures that delineate how the IDT will operate, how they will conduct participant assessments, and how they will incorporate the results of assessments into a continuously updated care plan for each participant. Specifically, the policies and procedures should address, at a minimum, the following elements:

- The mechanisms and timeframes for IDT interaction;
- The organization's process for initial assessment includes:
  - Discipline-specific assessment information and at what intervals assessments are made;
  - Criteria to determine when additional disciplines (i.e. Speech Therapist, medical specialists, clinical pharmacists, dentists, etc.) would be included in the assessment;
  - Required elements of the initial and periodic assessments, i.e., physical and cognitive function and ability, medication use, participant preferences for care, socialization and availability of family support, current health status and treatment needs, nutritional status, participant behavior, psychosocial status, medical and dental status, and participant language;
  - Home assessment including home access and egress, ability to perform ADLs in the home environment, need for assistive devices, ability to summon immediate emergency assistance, relationship with co-habitants and neighbors;
  - Identification of conditions that overlap disciplines (e.g., blindness, deafness, psycho-behavioral problems, etc) and require multidisciplinary interventions and measurable outcomes;
- The process for reassessments includes:
  - Frequency at which scheduled reassessments are performed;
  - Circumstances that would prompt an unscheduled reassessment (i.e., significant change in health status);
  - Persons performing the reassessment;
  - Process for communicating the compiled reassessment information to the team [42 CFR §460 Preamble Discussion];

- Process for resolving participant requests for reassessments in a timely manner [42 CFR §460.104(d)];
  - Team roles and functions;
  - Timeline;
  - Documentation of resolution.

[42 CFR §§ 360.102(e) and 460.104(d)(2)(i); 71 FR 71331 (Dec. 8, 2006)]

## **8.2.2 Timing of Assessments**

### **8.2.2.1 Pre Enrollment**

The IDT must perform any pre-enrollment assessments in person, and cannot substitute assessments completed by non-PACE community providers or reports contained in copied medical records. The PACE organization also cannot supplant the initial comprehensive assessments with any pre-enrollment screening undertaken to determine a prospective enrollee’s suitability for PACE services as well as eligibility for PACE enrollment.

CMS recognizes that some PACE organizations may choose to perform some or all IDT assessments prior to enrollment, and allows pre-enrollment assessments to fulfill the initial assessments requirement when certain contingencies are met:

- The health status of the enrolled participant has not changed since the pre-enrollment assessments;
- If the participant’s health status has changed, the participant is reassessed per 42 CFR § 460.104 and an initial care plan developed per 42 CFR § 460.106;
- The timing of the initial assessments does not adversely affect capitated payment to the organization.

### **8.2.2.2 Initial Assessment**

The interdisciplinary team (IDT) must conduct an initial comprehensive assessment in person on each participant. The initial comprehensive health assessment must be performed for each enrolled PACE participant must be completed promptly following enrollment, but individual team members’ in-person assessment of each participant should be scheduled at appropriate intervals based on the participant’s level of health. If the comprehensive assessment cannot be completed by the effective date of enrollment, , the organization must explicitly document the reason for the delay in the progress notes and care plan and perform the comprehensive assessment within a few days [42 CFR § 460.104(a)(2)].

CMS believes timely health assessments and care planning are imperative to sustain continuity of care. Therefore, if essential members of the IDT or other identified healthcare experts required to complete the initial comprehensive assessment are not available to conduct the assessment in the established time frame due to prolonged absence (vacant IDT position, extended leave, or illness lasting three or more weeks), the remaining IDT members should develop the care plan and revise it as soon as the missing required initial health assessment is completed, and document in the progress notes the reason for the delay in developing a complete care plan.

### **8.2.2.3 Assessment of Multiple New Participants**

When a PACE organization enrolls three or more new PACE participants in one month, the organization may conduct the initial comprehensive assessment for the new PACE participants over a four-week (i.e., twenty business days) time period in which the IDT identifies and prioritizes the assessments by highest acuity of care (i.e., sickest first).

If essential members of the IDT or other identified healthcare experts required to complete the initial comprehensive assessment are not available to conduct the assessment in the established time frame, the remaining IDT members should develop the care plan and revise it as soon as the missing required initial health assessment is completed, and document in the progress notes the reason for delay of care plan development. Following completion of the assessments for an individual participant, the IDT will promptly consolidate the discipline-specific results into a single plan of care.

## **8.2.3 Assessment Process**

### **8.2.3.1 Initial Assessment**

The initial comprehensive health assessment must be conducted in person by eight of the eleven IDT members for each new participant. Each IDT member uses a discipline-specific standardized health risk assessment form developed or adopted by the PACE organization. (Preamble discussion) When completed, the discipline-specific health risk assessment form is filed in the medical record section designated by PACE organization policy, for example, in a separate tab containing all discipline-specific assessments; or, in the respective discipline section of the medical record along with the discipline-specific progress notes. CMS expects clinical documentation to meet professional health information management standards. Specifically, clinical documentation must: a) identify and communicate patients' problems, needs and strengths; b) monitor their condition on an ongoing basis; and c) record treatment and response to treatment for each participant. PACE organizations must periodically review medical records to assure that clinical documentation reflects good clinical practice and conforms to high standards of communicating clear, complete, and accurate information at the level expected from trained and licensed health care professionals. Good clinical practice dictates not only the documentation of treatment and services, but also the outcomes and

efficacy in resolving the problem. Further information regarding medical records can be found in [Chapter 12](#).

A comprehensive assessment criterion includes, but is not limited to, the following:

- Physical and cognitive function and ability;
- Medication use;
- Participant and caregiver preferences for care;
- Socialization and availability of family support;
- Current health status and treatment needs;
- Nutritional status;
- Home environment, including home access and egress;
- Participant behavior;
- Psychosocial status;
- Medical and dental status;
- Participant language and cultural needs.

[42 CFR § 460.104(a)(2) and (4); 71 FR 71311 (Dec. 8, 2006) ]

### **8.2.3.2 Semiannual Reassessments**

The IDT primary care physician, registered nurse, master’s level social worker, and recreational therapist/activity coordinator must all minimally conduct periodic health reassessments on a semiannual basis. Other IDT members or specialty practitioners actively involved in the participant’s care plan should also conduct the semiannual reassessment. The pertinent practitioners conduct the reassessment in person, and meet to consolidate the reassessment findings into the care plan. At least semi-annually, the IDT must reevaluate the plan of care, including defined outcomes, and make changes as necessary.

<b>Intervals</b>	<b>Performed</b>	<b>Minimum disciplines involved</b>
Semi-annual	<ul style="list-style-type: none"> <li>• In-person</li> <li>• At least every 6 months</li> </ul>	<ul style="list-style-type: none"> <li>• PCP, RN, SW, Recreational Therapist or Activity Coordinator</li> </ul>

	<ul style="list-style-type: none"> <li>• More often if participant’s condition dictates</li> </ul>	<ul style="list-style-type: none"> <li>• Other team members actively involved in development or implementation of Plan of Care</li> </ul>
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[42 CFR §§ 460.104(c)(1) and 460.106(d)]

### 8.2.3.3 Annual Reassessments

The physical therapist, occupational therapist, dietitian, and home care coordinator must all minimally conduct on at least an annual basis, reassessment in person. Other pertinent IDT members or specialty practitioners actively involved in the participant’s care plan should also conduct an in-person annual reassessment. The IDT members who do the periodic reassessment must meet to consolidate the findings into the revised care plan.

Intervals	Performed	Minimum disciplines involved
Annual	<ul style="list-style-type: none"> <li>• In-person</li> <li>• At least annually</li> <li>• More often if participant’s condition dictates</li> </ul>	<ul style="list-style-type: none"> <li>• PT, OT, Dietitian, Homecare Coordinator</li> <li>• Other team members actively involved in development or implementation of POC</li> </ul>

[42 CFR § 460.104(c)]

### 8.2.3.4 Periodic and Unscheduled Health Reassessments

In addition to the semiannual and annual reassessments described above, two situations should trigger participant reassessment. First, if a participant experiences a significant change in health or psychosocial status, the eight IDT members (primary care physician, registered nurse, master’s level social worker, physical therapist, occupational therapist, recreational therapist or activity coordinator, dietitian, and home care coordinator) must conduct an in-person reassessment. Secondly, when a participant or his or her designated representative believes that the participant needs to initiate, eliminate, or continue a particular service, the IDT members will determine the pertinent practitioners to conduct the in-person reassessment. The PACE organization must have explicit procedures for timely resolution of requests by a participant or his or her designated representative to initiate, eliminate, or continue a particular service. The ITD must notify the participant or designated representative of its decision to approve or deny the request from the participant or designated representative as expeditiously as the participant’s condition requires, but no later than 72 hours after the date the IDT receives the request for reassessment. However, the IDT may extend the 72-hour timeframe for notifying the participant or designated representative of its decision to approve or deny the request by no more than 5 additional days if the participant or designated representative requests the extension or the IDT documents its need for additional information and how the delay is in the interest of the participant. The PACE organization must explain any denial of a request to the participant or designated representative orally and in writing. The PACE organization must provide the specific reasons for the denial in understandable language. The PACE organization is responsible for:

(1) informing the participant or designated representative of his or her right to appeal the decision; (2) describing both the standard and expedited appeals processes, including the right to, and conditions for, obtaining expedited consideration of an appeal of a denial of services; and (3) describing the right to, and conditions for, continuation of appealed services through the period of an appeal. If the IDT fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care, this failure constitutes an adverse decision, and the participant’s request must be automatically processed by the PACE organization as an appeal in accordance with § 460.122.

Intervals	Performed	Minimum Disciplines Involved
Unscheduled	<ul style="list-style-type: none"> <li>• In-person</li> <li>• Change in participant status (health or psychosocial)</li> <li>• At the request of the participant or designated representative</li> </ul>	<ul style="list-style-type: none"> <li>• PCP, RN, SW, Recreational Therapist/Activity Coordinator, PT, OT, Dietitian, and/or Homecare Coordinator as needed</li> <li>• Other team members actively involved in development or implementation of POC</li> </ul>

[42 CFR § 460.104(d)]

**8.2.3.5 Recommendations for the Assessment Process**

**8.2.3.6 Changes to Plan of Care and Documentation**

Team members who conduct a reassessment must meet the following requirements:

- Reevaluate the participant’s plan of care;
- Discuss any changes in the plan with the IDT;
- Obtain approval of the revised plan from the IDT and the participant (or designated representative); and
- Furnish any services included in the revised plan of care as a result of a reassessment to the participant as expeditiously as the participant’s health condition requires.

IDT members must document all assessment and reassessment information in the participant’s medical record.

[42 CFR § 460.104(e) and (f)]

**Section 3 - Care Planning**

## **8.3 Introduction**

### **8.3.1 PACE Care Planning Overview**

PACE care planning is the process by which a participant's IDT holistically assesses the participant's medical, functional, psychosocial, and cognitive needs, and develops a single comprehensive plan of care to address the identified needs. The IDT members who conduct the extensive discipline-specific assessments collectively discuss the participant's identified needs, and design and monitor the individualized care plan.

[42 CFR §§ 460.104 and 460.106(b)]

### **8.3.2 PACE Care Planning and the Interdisciplinary Team**

PACE care planning is the responsibility of the IDT members that deliver direct care to participants in the PACE center they attend and/or in alternative settings such as their homes or inpatient facilities when dictated by their healthcare needs. A key component of the PACE model is IDT members' identification of participant needs in all care domains (medical, psychosocial, physical, cognitive, functional, and end-of-life), and the IDT's coordinated response to these needs. Each member of the team acts within his/her authorized scope of practice, in accordance with participant preferences, working in unison with other IDT members to meet the identified needs and achieve each participant's optimal outcomes. Optimal outcomes will differ for each participant, but the plan of care is the roadmap to meet the member- and team-defined outcomes as measured after implementation of focused interventions over a prescribed period of time.

Each participant is assigned at enrollment to an IDT team that operates at the PACE center the participant attends. The intent of having this broad-based team is to maximize the expert services dedicated to the holistic care of each participant.

[42 CFR § 460.104][42 CFR § 460.106]

### **8.3.3 Plan of Care Development [42 CFR § 460.106]**

#### **8.3.3.1 Single Plan of Care**

The IDT will promptly consolidate the eight discipline-specific assessments into a single individualized plan of care for each participant. The full IDT team collectively develops the care plan through discussion and consensus at a formal care planning meeting. The IDT must implement, coordinate, and monitor the plan of care whether the services are furnished by PACE employees or contractors. When goals and interventions for a particular problem are overlapping, the team may decide to combine actions into team interventions and outcomes to achieve a single goal. They may conversely find that a problem is unique and needs to be

addressed by a specific discipline. Whether a problem manifests as multi-faceted or singular in nature, the IDT incorporates the problems into a single plan of care that is collectively monitored and evaluated by the team. Although the PACE center director, driver, and personal care attendant do not perform assessments, they contribute valuable information about participants and should be included in care planning discussions [42 CFR § 460.106].

[42 CFR §§ 460.104(b) and 460.106(a) and (c)]

### **8.3.3.2 Participant / Caregiver Involvement in Care Planning Process**

The IDT must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver, or both, to ensure that there is agreement with the plan of care and that the participant's concerns are addressed. The IDT may subsequently need to reconvene to incorporate information obtained from the participant and/or caregiver related to care plan changes requested by the participant.

[42 CFR § 460.106(e)]

### **8.3.3.3 Contents of the Plan of Care**

The initial care plan must specify the care needed to meet the participant's medical, functional, emotional, social, and cognitive needs identified in the initial comprehensive health assessment. For each need identified, the plan must state the problem, interventions to resolve or mitigate the problem, the measurable outcomes to be achieved by the interventions, the anticipated time lines in which to achieve the desired outcomes, and the staff responsible for conducting the interventions and monitoring the outcomes. All care plans should include the aforementioned basic five components; however, experienced PACE organizations may design more sophisticated care plan models that incorporate these five basic components with other features such as long-term and short-term goals that enhance care management.

The PACE plan of care is the IDT's framework for managing the overall health status of each participant. The problems identified in the initial health risk assessment and the IDT's coordination of care will be the plan's focus. In general, the plan includes:

- Active chronic problems for which the IDT members have designed interventions that they will be monitoring and evaluating over a set time frame. When the IDT members achieve the care goals for an active problem, they may classify the problem as maintenance care. Maintenance care may be addressed in the care plan or in the discipline-specific progress notes depending on the organization's policy;
- Problems that cross domains of care and require multidisciplinary coordination;

- Exacerbation of problems that were previously controlled and/or classified as maintenance care, but disease progression and/or other intervening conditions resulted in a change that now requires team monitoring and evaluation of interventions;
- Significant changes that indicate a decline or improvement in health status that:
  - o Will not normally resolve without intervention by providers, require standard disease-related clinical interventions, or are not self-limiting;
  - o Impacts more than one area of the patient’s health status, and
  - o Requires interdisciplinary review and/or revision of the care plan.

Each PACE organization must define what care is integrated into the participant’s plan of care, and what discipline-specific care is appropriately documented and monitored by the respective discipline specialist in the progress notes.

As PACE organizations develop care planning policy and procedures that unequivocally define what problems are incorporated in the single care plan versus which problems may be documented solely in discipline-specific progress notes, the following criteria are suggested:

- Long-standing stability (e.g., controlled over several months or years) versus liability (e.g., uncontrolled or prone to exacerbations);
- Brevity of therapeutic regimen to achieve resolution (e.g., brief regimen of one-two weeks) versus chronicity of therapeutic regimen with uncertain course until resolution (e.g., repeated changes in therapeutic agents to achieve resolution);
- Maintenance condition monitored by a sole discipline versus active condition that has potential to result in a change in health status, change in medication, or expanded therapeutics requiring multidisciplinary monitoring;
- Stable residential, social network and caregiver support versus residential or psychosocial transitions requiring multidisciplinary monitoring.

[42 CFR § 460.106(b)]

#### **8.3.3.4 Differentiating Progress Notes and Care Plan Contents**

The participant medical record is the single comprehensive record of care rendered to an individual participant. A PACE organization must maintain a single, comprehensive medical record for each participant, in accordance with accepted professional standards. The medical record must be complete, accurate, readily accessible, systematically organized, available to

all staff, and maintained and housed at the PACE center where the participant receives services. Each participant record must contain all of the essential components listed in 42 CFR §460.210(b) including the eight IDT discipline-specific initial assessments and all reassessments, discipline-specific progress notes, and the participant's single plans of care.

[42 CFR § 460.210(a) and (b)]

### **8.3.4 Monitoring Participant Health Status**

The IDT members must continuously monitor the participant's medical, functional, emotional, social, and cognitive status. IDT members monitor health status by direct observation when providing services, informal observation in the PACE center or alternative settings, self-report by participants, feedback from caregivers, reports from network providers, or communication among IDT members. When significant health or psychosocial status changes occur, the pertinent IDT members must reassess the participant and initiate or expand an already scheduled care planning meeting to discuss the significant change(s), the reassessment results, and, if warranted, revise the participant's care plan following the discussion. Significant changes are defined as a "decline" or "improvement" in the last assessed health status that meets all three conditions:

- Will not normally resolve without intervention by staff or by implementing standard disease-related clinical interventions and is consequently not "self-limiting";
- Impacts more than one domain of the participant's health;
- Requires interdisciplinary review and/or revision of the care plan.

[42 CFR §§ 460.104(d)(1) and (e) and 460.106(c)(2)]

### **8.3.5 Documentation of Plan of Care**

The IDT members consolidate the contents of the PACE care plan into a single comprehensive document that is filed in the care plan section of the participant's medical record. The care plan clearly displays, at a minimum, the problem being addressed, interventions, measurable outcomes, time lines, and persons responsible for each intervention. It is continuously updated as the team monitors the participant's health status. Updates are made directly to the care plan in a way that preserves the history of care and enables the team to trace the effectiveness of interventions over time.

[42 CFR § 460.106(f)]

### **8.3.6 Plan of Care Revision**

The PACE care plan is continuously updated as the team monitors the participant's health status. The IDT members must minimally reevaluate the single comprehensive plan of care for each participant on a semiannual basis. The team should conduct the reevaluation in collaboration with the participant and caregivers whenever feasible. Involvement of the participant and caregivers in care planning assures that the participant's care preferences are addressed and informed participation in care is maximized.

Updates are made directly to the care plan in a way that preserves the history of care and enables the team to trace the effectiveness of interventions over time. New problems are added as they are identified, and resolved problems may be retained for monitoring or relocated to the discipline-specific progress notes if the team classifies it as maintenance care. The rationale for eliminating or relocating a resolved problem to maintenance care in the progress notes section must be documented in the care plan.

[42 CFR §§ 460.104(c)(1) and (e) and 460.106(d)]

### **8.3.7 Continuous Plan of Care Monitoring and Evaluation**

An integral part of implementing the care plan is the IDT's continuous monitoring of the participant's health and psychosocial status as well as the effectiveness of the plan of care. Continuous monitoring is achieved through the assessment/reassessment of participant needs, provision of services, formal evaluation of the efficacy of services provided, informal observation, input from participants or caregivers, and communication among IDT members and all other providers. Timely, accurate, and complete written and verbal communication among PACE stakeholders is paramount to quality and safe participant care. The interdisciplinary care team approach and the perpetual care planning process are the gold standards that make PACE an effective model for the care of frail elders.

[42 CFR § 460.106(c)(2)]

**To obtain more information, please visit <http://www.cms.gov/pace/>.**

## Chapter 9 - PACE Organization's Relationship with Health Care Providers

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### Table of Contents

<a href="#"><u>9.1 Employed Direct Care Providers</u></a>	87
<a href="#"><u>9.1.1 Requirements for Employment</u></a>	87
<a href="#"><u>9.1.1.1 IDT Qualifications</u></a>	87
<a href="#"><u>9.1.1.2 Staff and Contractor Competencies</u></a>	89
<a href="#"><u>9.1.1.3 Competency Assessment</u></a>	89
<a href="#"><u>9.2 Requirements for Employees and Contracted Staff</u></a>	90
<a href="#"><u>9.2.1 Orientation and Training</u></a>	90
<a href="#"><u>9.2.1.1 Orientation</u></a>	91
<a href="#"><u>9.2.1.2 Personal Care Aide (PCA) Training</u></a>	92
<a href="#"><u>9.2.1.3 All Personnel: Direct Participant Care Training</u></a>	92
<a href="#"><u>9.2.1.4 Immunization and Physical Health</u></a>	93
<a href="#"><u>9.3 Contract Providers</u></a>	94
<a href="#"><u>9.3.1 Requirements for Written Contracts and Contract Requirements</u></a>	95
<a href="#"><u>9.3.2 Requirements of Contract Providers and Vendors</u></a>	96
<a href="#"><u>9.3.3 Requirements of Institutional Contractors, and Practitioners or Suppliers</u></a>	96
<a href="#"><u>9.4 Special Rules for Services Furnished by Non-contract Providers</u></a>	97
<a href="#"><u>9.5 Contracting with another Entity to Furnish PACE Center Services</u></a>	98
<a href="#"><u>9.6 Documenting Contractor Compliance</u></a>	98

## **9.1 Employed Direct Care Providers**

### **9.1.1 Requirements for Employment**

Each member of the PACE organization's staff who has direct participant contact (employee or contractor) must:

- Have a minimum of one year of experience working with the frail or elderly population including the Primary Care Physician (PCP);
- Be medically cleared of all communicable diseases and have all immunizations up-to-date before engaging in direct participant care;
- Be legally authorized (licensed, certified or registered) to practice in the State in which they practice if the State has established requirements or they must meet the State requirements that authorize them to practice in their State; and
- Only act within the scope of his or her authority to practice;
- Meet standardized competencies for the specific position description established by the PACE organization and approved by CMS before working independently (only applies to home care aides).

The PACE organization must ensure that these requirements are met and, as discussed in section 9.1.1.2, have policies and procedures regarding these requirements.

In order to maintain compliance with program integrity the PACE organization must:

- Not employ individuals excluded from participation in the Medicare or Medicaid programs;
- Not employ individuals convicted of Medicare, Medicaid, or other health insurance or health care programs, or any social service program related crimes;
- Not employ individuals convicted of physical, sexual, drug, or alcohol abuse.

[42 CFR §§ 460.64(a) and 460.68(a)]

#### **9.1.1.1 IDT Qualifications**

The IDT is critical to the success of the PACE program. In addition to the criteria in section 9.1.1 above, the specific personnel qualifications for the IDT include, but are not limited to, the following:

- **Primary Care Physician.** Primary care physician must have a minimum of one year's experience working with a frail or elderly population;
- **Registered Nurse.** A registered nurse must be a graduate of a school of professional nursing;
- **Social Worker.** A social worker must have a master's degree in social work from an accredited school of social work;
- **Physical Therapist.** A physical therapist must be a graduate of a physical therapy curriculum approved by one of the following:
  - The American Physical Therapy Association;
  - The Committee on Allied Health Education and Accreditation of the American Medical Association; or
  - The Council on Medical Education of the American Medical Association and the American Physical Therapy Association or other equivalent organizations approved by CMS;
- **Occupational Therapist.** An occupational therapist must meet the following requirements:
  - Be a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association or other equivalent organizations approved by the Secretary;
  - Be eligible for the National Registration Examination of the American Occupational Therapy Association; and
  - Have two years of appropriate experience as an occupational therapist and have achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that the determination of proficiency does not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist after December 31, 1977;
- **Recreation Therapist or Activities Coordinator.** A recreation therapist or activities coordinator must have two years experience in a social or recreational program providing and coordination services for a frail or elderly population within the last five years, one year of which was full-time in a patient activities program in a health care setting;

- **Dietitian.** A dietitian must have a baccalaureate or advanced degree from an accredited college with major studies in food and nutrition or dietetics;
- **Drivers.** A PACE center driver must meet the following requirements:
  - Have a valid driver's license to operate a van or bus in the State of operation; and
  - Be capable of, and experienced in, transporting individuals with special mobility needs.

[42 CFR § 460.64(b); 71 FR 71266 (Dec. 8, 2006)]

### **9.1.1.2 Staff and Contractor Competencies**

In order to comply with PACE requirements, it is recommended that the PACE organizations have a policy and procedure in place for assuring that staff and contractors:

- Are legally authorized (licensed, certified, registered) to practice in the State in which they provide services;
- Meet State requirements that authorize them to provide services; and,
- They only act within the scope of his or her authority to practice.

The policy and procedures would also demonstrate that the PACE organization has a system for updating staff competency information, and discloses, upon request, information regarding:

- Board certification and other credentialing requirements;
- Clinical protocols;
- Medical practice guidelines, consumer satisfaction survey results; or
- The results of the organization's most recent Federal or State review.

PACE organizations may wish to refer to credentialing guidance in the Medicare Managed Care Manual for a description of one option on which to build the policy and procedure (<http://www.cms.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS019326&intNumPerPage=10>).

[42 CFR § 460.64]

### **9.1.1.3 Competency Assessment**

The PACE organization must develop a competency evaluation program to ensure all employees and contracted staff providing direct care to participants can demonstrate the skills, knowledge and abilities necessary for performance of their position. The PACE organization must designate a staff member to oversee these activities for employees and work with the PACE contractor liaison to ensure compliance by contracted staff. The competency evaluation program must be completed by each employee prior to providing direct participant care. An employee demonstrating competence for their position is essential to ensure the delivery of safe care.

All personnel, including personal care attendants, need to meet the credentialing criteria and a standardized set of competencies for their specific position prior to their engaging in direct participant care. The PACE organization's competency evaluation program must:

- Describe the minimum skills necessary to perform each specific job;
- Describe the process for initially testing competency;
- Identify the individual(s) responsible for competency testing for employees;
- Identify the individual designated to work with the PACE contractor liaison to ensure compliance by contracted staff;
- Explain how the PACE organization will resolve competency deficiencies.

The PACE organization must conduct an annual competency review with their employees, including personal care attendants. The PACE organization's annual competency review program will:

- Describe the periodic competency review program;
- Identify who is responsible for periodic competency review;
- Explain how the PACE organization will resolve competency deficiencies.

[460 CFR § 460.66(a) and (c) and 460.71(a)]

## **9.2 Requirements for Employees and Contracted Staff**

### **9.2.1 Orientation and Training**

The PACE organization is required to provide training to maintain and improve the skills and knowledge of each staff member with respect to the individual's specific duties that result in his or her continued ability to demonstrate the skills necessary for the performance of the position.

The PACE organization must ensure that all employees and contracted staff furnishing care directly to participants, demonstrate the skills necessary for performance of their position. The PACE organization must provide each employee and all contracted staff with an orientation. The orientation must include, at a minimum, the organization's mission, philosophy, policies on participant rights, emergency plan, ethics, the PACE benefit and any policies related to the job duties of specific staff.

The PACE organization must develop a training program that will:

- Identify the person and position responsible for the overall training program;
- Describe the content of the training program including initial orientation and periodic refresher training including PACE-specific topics and position-specific topics;
- Describe the instructors, methods of teaching, methods of testing, and results of any testing (written or oral); and
- Discuss how the PACE organization will resolve knowledge deficits.

[42 CFR §§ 460.66(a) and 460.71(a)(1)]

### **9.2.1.1 Orientation**

The PACE organization must provide a comprehensive orientation program to each employee and all contracted staff. Documentation of completion date(s) for each and every component of the orientation must be maintained in staff records. This orientation must be provided prior to personnel engaging in direct participant care. The orientation must include at a minimum the organization's mission, philosophy, policies on participant rights, emergency plan, ethics, the PACE benefit, and any policies related to the job duties of specific staff. Additionally,, the orientation may include but isn't limited to:

- Role of the team;
- Organizational Chart: who everyone is on the team and the center;
- Standards of care and conduct;
- QI program: overview, principles, the staff role;
- List of providers;
- OSHA, standard precautions, infection reporting, waste management;

- Participant Safety ;
- Care of the elderly ;
- Training on medical equipment used in the PACE organization;
- Body mechanics;
- Personnel policies;
- Medical documentation requirements.

[42 CFR § 460.71(a)]

### **9.2.1.2 Personal Care Aide (PCA) Training**

In addition to the general training program, the PACE organization must develop a training program for each directly employed and contracted PCA in order to establish the individual's baseline competency in furnishing personal care services and specialized skills associated with the specific care needs of individual participants. The training plan must indicate how each skill is tested to determine the PCA's initial and ongoing competency. The PACE organization must evaluate the skills of each newly hired PCA and develop a training program specific to the competencies or deficiencies that they demonstrate. PCAs must exhibit competency before performing personal care services independently. A process must be in place for monitoring ongoing competency assessments and identify the individual responsible for supervising PCAs. This training must be performed by qualified professionals. The personnel file must contain the results of any testing, both written and oral.

[42 CFR § 460.66(b) and (c)]

### **9.2.1.3 All Personnel: Direct Participant Care Training**

The PACE organization must provide ongoing training to maintain and improve the skills and knowledge of each employee and contracted staff member with respect to their specific duties in order to ensure that PACE participants receive the highest quality care possible. A PACE organization has the ultimate responsibility for all care provided to their participants and, therefore, it is in the best interest of PACE participants and the PACE organization that they provide training specific to their participant population. Ongoing in-service training for all staff will ensure that skills remain current and any detrimental practices are caught and rectified as early as possible.

Annual training must be related to specific positions which include relevant topics. Training needs to be staggered throughout the year to enable all staff to participate. The training

program needs to describe plans for in-service training, the methods of teaching including handouts, pre and post test, if applicable, and the person/position conducting the training. Some PACE organizations may have the ability to use the health care facility to which they are related or they may use an outside agency for training purposes.

OSHA training must be provided on hire and annually is required, [29 CFR 1910.1030(g)(2)] by a qualified trainer. The employee cannot be given a manual, pamphlet or policy to read. This training must be given in an interactive session with a trainer present.

[42 CFR §§ 460.66(a) and 460.71]

#### **9.2.1.4 Immunization and Physical Health**

The PACE regulation stipulates that the PACE organization must develop and implement an infection control plan having specific procedures to prevent, identify, investigate, and control infections. Specifically, this regulation mandates compliance with the standard precautions developed by the Center for Disease Control and Prevention (CDC). A primary standard precaution in caring for the frail elderly population is immunization of healthcare workers. The CDC strongly recommends that healthcare workers be immunized against hepatitis B virus, influenza, measles, mumps, rubella, and varicella to protect them from acquiring or transmitting these vaccine-preventable infections.

The PACE organization must also include procedures in its infection control plan to prevent healthcare workers from acquiring or transmitting tuberculosis and bloodborne pathogens. In the exposure control section of the infection control plan, the PACE organization must identify the specific job classifications that perform duties in which exposure to active tuberculosis disease or bloodborne pathogens occurs. In a typical PACE organization, most, if not all, healthcare workers deliver direct care services to participants and should be classified as at-risk for exposure to these pathogens.

Pursuant to CDC recommendations, CMS issued regulation [42 CFR § 460.64(a)(5)] which states that staff having direct participant contact must be “medically cleared for communicable diseases and have all immunizations up to date before engaging in direct participant contact.” To meet this regulation, CMS expects the PACE organization to; at a minimum, take the following actions:

- Develop and implement policies and procedures to assure medical clearance during the pre-employment period. Medical clearance refers to appropriate management of:
  - Respiratory infections - appropriate precautions such as wearing face masks or other personal protective equipment (PPE) or delaying the start date for providing direct care when prospective employees present with respiratory infections, i.e., common colds, pneumonia, etc., which are transmittable through close contact;

- Skin infections – appropriate precautions such as requiring the covering of open and seeping lesions or delaying the start date for providing direct care when prospective employees present with skin infections, i.e., methicillin-resistant *Staphylococcus aureus* (MRSA), varicella zoster (shingles), pediculosis (lice infestation) etc., which are transmittable through close contact;
- Gastrointestinal infections – appropriate precautions such as delaying the start date for providing direct care when prospective employees present with gastrointestinal (GI) symptoms such as active vomiting or diarrhea related to acute viral hepatitis, food-borne bacterial infections, etc., which are transmittable through close contact;
- The PACE organization must determine the methodology (medical history tool, interview by clinician, etc.) by which it will assure that participants and other healthcare workers at the facility have protection in the workplace from exposure to infectious diseases. The State Administering Agency and jurisdictional public health agency may be important resources in developing these policies and procedures;

Develop and implement policies and procedures to assure appropriate healthcare worker immunization.

Additional information on CDC recommendations for immunizations of staff can be found at the following links:

Centers for Disease Control and Prevention, Immunization of Health-Care Workers: recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). MMWR 1997;46(No. RR-18): <http://ftp.cdc.gov/pub/Publications/mmwr/rr/rr4618.pdf>.

Centers for Disease Control and Prevention, Protecting Health Care Workers: <http://www.cdc.gov/ncidod/dhqp/worker.html>.

Centers for Disease Control and Prevention, Influenza Vaccination of Health-Care Personnel: recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP): <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm>.

Centers for Disease Control and Prevention, Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005. MMWR 2005;54(No. RR-17): <http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf>.

### 9.3 Contract Providers

The PACE organization must develop a policy and procedure that provides for formal oversight activities such as periodic observation of service delivery, review of service documentation, assurance of participation in refresher training, and review of applicable credentials.

### **9.3.1 Requirements for Written Contracts and Contract Requirements**

The PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization except for emergency services. A current list of contractors must be on file at the PACE center and a copy must be provided to anyone upon request.

Each contract needs to be in writing and contain the following information:

- Name of contractor;
- Services furnished (including work schedule if appropriate);
- Payment rate and method; and
- Terms of the contract, including the beginning and ending dates, as well as methods of extension, renegotiation, and termination.

A contract between a PACE organization and a contractor must meet the following requirements:

(1) The PACE organization must contract only with an entity that meets all applicable Federal and State requirements, including, but not limited to, the following:

- An institutional contractor, such as a hospital or skilled nursing facility, must meet Medicare or Medicaid participation requirements;
- A practitioner or supplier must meet Medicare or Medicaid requirements applicable to the services it furnishes;
- A contractor must comply with the requirements of this part with respect to service delivery, participant rights, and quality assessment and performance improvement activities;

(2) A contractor must be accessible to participants, located either within or near the PACE organization's service area; and

(3) A PACE organization must designate an official liaison to coordinate activities between contractors and the organization.

[42 CFR § 460.70(a), (b), (c), and (d)(1) through (4)]

### **9.3.2 Requirements of Contract Providers and Vendors**

In addition to the contract requirements in section 9.3.1 above, a contractor agreement must include the following written requirements for the contractor to adhere to:

- Furnish only those services authorized by the PACE IDT;
- Accept payment from the PACE organization as payment in full and not bill participants, CMS, the State Medicaid agency or private insurers;
- Hold harmless CMS, the State and PACE participants if the PACE organization cannot or will not pay for services performed by the contractor under the contract;
- Not assign the contract or delegate duties under the contract unless prior written approval is obtained from the PACE organization;
- Submit reports as required by the PACE organization;
- Agree to perform all the duties related to its position as specified in part 460;
- Participate in IDT meetings as required;
- Agree to be accountable to the PACE organization; and
- Cooperate with the competency evaluation program and direct participant care requirements specified in § 460.71.

[42 CFR § 460.70(d)(5)]

### **9.3.3 - Requirements of Institutional Contractors, and Practitioners or Suppliers**

Institutional providers include but are not limited to:

- Acute care hospitals;
- Rehabilitation hospitals and distinct part rehabilitation units of acute care hospitals;
- Psychiatric hospitals and distinct part psychiatric units of acute care hospitals; and
- Critical access hospitals, nursing facilities and skilled nursing facilities.

The PACE organization must contract only with institutional entities that meet all applicable Federal and State requirements as well as meet the Medicare and Medicaid participant requirements. There is provider specific Conditions of Participation for institutions that participate in the Medicare program. Therefore, all institutional contractors must be in compliance with their respective Conditions of Participation.

A practitioner or supplier must meet Medicare or Medicaid requirements applicable to the services it furnishes.

#### **9.4 Special Rules for Services Furnished by Non-contract Providers**

Services a participant may need while temporarily absent from the PACE organization's service area that are not emergency services but cannot be delayed until the participant returns would need prior authorization.

A PACE organization must establish a written plan for handling emergency health care needs. The plan must include that the participants and their caregiver know:

- When and how to access emergency services;
- That no prior approval is necessary for emergency services;
- That CMS, the State and PACE participants are held harmless for emergency services;
- That the PACE organization must provide for availability of on-call providers to address any participant questions about accessing emergency services and respond to requests for authorization of urgently needed out-of network services or post-stabilization.

Listed below are the types of services that fall under this special rule category:

- Emergency care is appropriate when services are needed immediately because of an injury or sudden illness and the time required to reach the PACE organization or a network provider would cause the risk of permanent damage to the participant's health. Thus, emergency care services include inpatient and outpatient services, furnished by a qualified emergency services provider (other than the PACE organization or one of its contract providers) either in or out of the PACE organization's service area and that are needed to evaluate or stabilize an emergency medical condition. Emergency services that fall within this description do not require authorization by the PACE organization. Determination of the need for emergency care is dependent on the prudent layperson standard with average knowledge of health and medicine;

- Urgent care means the care provided to a PACE participant who is out of the PACE services area, and who believes their illness or injury is too severe to postpone treatment until they return to the service area, but their life or functioning is not in severe jeopardy. Participants are expected to seek prior approval from the PACE organization in order for urgent care services to be covered by the PACE organization;
- Post-stabilization care means services provided subsequent to an emergency that a treating physician views as medically necessary after an emergency medical condition has been stabilized. They are not emergency services, which PACE organizations are obligated to cover. Rather, they are non-emergency services that the PACE organization should approve before they are provided outside of the service area. Prior approval of these services is intended to ensure efficient and timely coordination of appropriate post emergency care by the IDT. In order to ensure that unforeseen circumstances do not result in delays in needed care, CMS clarified that the PACE organization must cover urgently needed out-of-network or post-stabilization care services if it does not respond to a request for approval within one hour after being contacted or cannot be contacted for approval.

[42 CFR § 460.100(b), (c), (d) and (e); 71 FR 71284 (Dec. 8, 2006)]

## **9.5 Contracting with another Entity to Furnish PACE Center Services**

The PACE organization must meet certain criteria to contract out PACE center services. The following criteria must be included:

- Any subcontracting arrangements by the PACE center would need to be approved in writing by the PACE organization;
- The PACE organization must be fiscally sound as defined in § 460.80(a) and have demonstrated competence with the PACE model as evidenced by successful CMS and State onsite reviews and monitoring efforts.

The PACE organization retains responsibility for all participants and may only contract for the PACE center services identified in 42 CFR § 460.98(d) as described in detail in [Chapter 6](#), which include: primary care; social services; restorative therapies; personal care and supportive services; nutritional counseling; recreational therapy; and, meals.

[42 CFR § 460.70(e)]

## **9.6 Documenting Contractor Compliance**

The burden of documenting contractors' compliance with applicable standards ultimately rests with the organization.

It is especially important to identify specific responsibilities of a contractor. The PACE organization must develop its own procedures to ensure that the entity complies with the standards of competency and quality of care.

The PACE organization must not contract with organizations or individuals who have been excluded from the Medicare or Medicaid programs; who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, other health insurance or health care programs, or social service programs under title XX of the Act; or for those having participant contact, would pose a potential risk because of prior physical, sexual, drug, or alcohol abuse conviction.

The PACE organization must contract with only those entities that meet all applicable Federal and State requirements.

All employees and contractors must meet the personnel qualifications for the physician, registered nurse, social worker, physical therapist, occupational therapist, recreational therapist, dietitian and driver.

Although the organization is not performing the actual compliance checks (in the case of a hospital, physician, medical equipment, or supplies), the organization must ensure that the contractor is in compliance with the written contract. The written contract must state that the contractor will meet all applicable Federal and State requirements allowing the PACE organization some flexibility in determining the organizational process that will occur to ensure their contractors meet all program requirements.

In the case of an independent contractor or provider based organization that has not been credentialed through a Medicare or Medicaid contracting organization, the PACE organization will have to receive the same documents from the contractor as they would for an employee. If the contractor is working for the contracted organization and not independently, then the contracted organization must forward all of their staff credentials prior to performing participant care.

The PACE organization is responsible for not only ensuring the contract staff meet requirements at the onset of the contract, but on an ongoing basis. The contract organization has to have a process in place to ensure this compliance and the PACE organization has to have a process to review contract compliance. The contract organization must have a process in place to notify the PACE organization when one of their staff is out of compliance so that the PACE organization does not utilize that staff member for participant care (in the case of license expiring or other sanctions, illegal activity).

[42 CFR §§ 460.64, 460.68(a), and 460.70(b)(1)]

## Chapter 10 - PACE Quality Assessment and Performance Improvement

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### Table of Contents

<a href="#"><u>10.1 Introduction</u></a>	101
<a href="#"><u>10.2 Quality Assessment and Performance Improvement (QAPI) Program</u></a>	101
<a href="#"><u>10.2.1 QAPI Plan</u></a>	101
<a href="#"><u>10.2.2 QAPI Requirements</u></a>	102
<a href="#"><u>10.2.3 Internal QAPI Activities</u></a>	104
<a href="#"><u>10.2.4 QAPI Committee</u></a>	105
<a href="#"><u>10.3 Additional Quality Assessment Activities</u></a>	106
<a href="#"><u>10.3.1 External Reporting Requirements</u></a>	106
<a href="#"><u>10.3.1.1. Level One Reporting</u></a>	107
<a href="#"><u>10.3.1.2. Level Two Reporting</u></a>	108
<a href="#"><u>10.3.1.2.1 Reporting Requirements of Level Two Incidents</u></a>	109
<a href="#"><u>10.3.1.2.2 Process for Conducting Root Cause Analysis</u></a>	110
<a href="#"><u>10.3.1.2.3 Format for Level Two PACE Organization Conference Call Case Presentation</u></a>	112
<a href="#"><u>10.3.1.3 Health Outcomes Survey - Modified (HOS – M)</u></a>	113
<a href="#"><u>10.3.1.3.1 Medicare HOS-M Sampling</u></a>	113
<a href="#"><u>10.3.1.3.2 HOS-M Instrument</u></a>	113
<a href="#"><u>10.3.1.3.3 Dissemination of HOS-M Results to Plans</u></a>	114
<a href="#"><u>10.3.1.3.4 HOS-M Program or Policy Questions</u></a>	114
<a href="#"><u>10.3.1.4. Additional Required Reporting</u></a>	114

## **10.1 Introduction**

Title 42 CFR § 460, Subpart H – Quality Assessment and Performance Improvement (QAPI), establishes the quality improvement program requirements that the Program of All-Inclusive Care for the Elderly (PACE) organizations must meet under the Social Security Act (the Act). Furthermore, Sections 1894(e)(3)(B) and 1934(e)(3)(B) of the Act require that, under a PACE Program Agreement, the PACE organization, the CMS, and the State Administering Agency shall jointly cooperate in the development and implementation of health status and quality of life outcome measures with respect to PACE participants.

## **10.2 QAPI Program**

The PACE organization must develop, implement, maintain, and evaluate an effective data-driven QAPI program. It is important that the QAPI program reflects the full range of services furnished by the PACE organization. In developing the QAPI program, the PACE organization should use organizational data to identify and improve areas of poor performance. The PACE organization must take actions that result in improvements in its performance in all types of care.

Currently, CMS does not require the use of a common quality assessment tool or a set of specific outcome measures beyond the data elements for monitoring included in the program agreement. PACE organizations have the flexibility to develop the QAPI program that best meets their needs in order that they may fully meet the obligations of care for its participants. It is CMS' expectation that PACE organizations will operate a continuous QAPI program that does not limit activity to only selected kinds of services or types of patients. The desired outcome of the QAPI requirement is that data-driven quality assessment serves as the engine that drives and prioritizes continuous improvements for all the PACE organizations services (42 CFR 460 Preamble Discussion/Federal Register December 8, 2006).

[42 CFR § 460.130; 71 FR 71305 (Dec. 8, 2006)]

### **10.2.1 QAPI Plan**

The PO must have a written QAPI plan. Consistent with the Protocol, we require POs to have their QAPI plan annually reviewed by the PACE governing body and, if necessary, revised.

At a minimum, the PACE organization's QAPI plan must 1) identify areas in which to improve or maintain the delivery of services and patient care; 2) develop and implement plans of action to improve or maintain quality of care; and 3) document and disseminate the results of the QAPI activities to the PACE staff and contractors.

As per 42 CFR § 460.132(a)(b), the PACE organization leadership presents their QAPI plan and any revisions to their governing body for annual approval to assure effective organizational oversight. CMS and the State Administering Agency approve the QAPI plan

prior to its inclusion in the program agreement and also review the plan during subsequent monitoring visits.

[42 CFR § 460.132]

### **10.2.2 QAPI Requirements**

Through the QAPI program, PACE organizations should evaluate the effectiveness of the wide range of services furnished by PACE organizations; and use data to identify and improve areas of poor performance. CMS believes that each PACE organization should have the flexibility to design an internal QAPI that would best meet the needs of its enrolled participants and their caregivers; therefore, CMS neither specified a standardized quality assessment tool nor dictated the data-driven outcome measures that PACE organizations should internally collect, analyze, and act on to improve performance. However, CMS did provide in 42 CFR § 460.132 (and discussed in section 10.2.1) the minimum requirements that must be addressed in the PACE organization's written plan for the internal QAPI program including the requirement that the plan be annually reviewed and revised by the respective PACE governing body to assure organizational oversight and commitment.

A PACE organization's QAPI program must include, but not be limited to, the use of objective measures to demonstrate improved performance with regard to five areas: 1) utilization of services (e.g., decreased inpatient hospitalizations and emergency room visits), 2) participant and caregiver satisfaction, 3) outcome measures that are derived from data collected during participant assessments, 4) effectiveness and safety of staff-provided and contracted services, and 5) non-clinical areas including grievances and appeals.

- **Utilization of Services.** Collected utilization data such as hospitalizations and emergency room visits can be used to evaluate fiscal well-being, as well as evaluate quality of care. It can also be used to target reviews of PACE centers whose utilization data suggest, for example, that participants may be receiving fewer services than necessary to achieve expected outcomes. The purpose for including utilization data in the PACE organization's QAPI program is to help the PACE organization ensure that participants receive the appropriate level of care through their PACE center. Additionally, using information regarding utilization of and reasons for emergency care and hospital and nursing home admissions, the PACE organization can identify areas for improvement;
- **Participant and Caregiver Satisfaction.** Participant and caregiver satisfaction with services is an important element of a QAPI program. A PACE organization must survey, on an ongoing basis, participants and their caregivers to determine satisfaction with the services furnished and the outcomes achieved. Given the large number of PACE participants who are cognitively impaired and the critical role caregivers' play in keeping PACE participants in the community, it is important to survey caregivers about their satisfaction with the program. CMS expects the PACE

organization to use this information to identify opportunities to improve services and caregiver and participant satisfaction. Although CMS does not require the use of a specific survey tool in measuring participant and family satisfaction, the PACE organization is expected to demonstrate a scientifically sound satisfaction measurement system and how it is used as part of the overall internal QAPI system;

- **Data Collected During Participant Assessments.** Outcome measures are derived from participant assessment data to determine if individual and organization-level measurable outcomes are achieved within a specified time period. The compiled data must include, at a minimum, the physiological well-being, functional, mental health, social and behavioral status, cognitive ability, and quality of life of the participant assessment information;

For example, PACE organizations are expected to focus their quality improvement activities on outcomes such as stabilization in ability to bathe, from a baseline period to each follow-up period; improvement in dyspnea from admission into PACE to a follow-up period; improvement in transportation services over a specific period of time; and improvement in caregiver stress from participant admission into PACE to a follow-up period (42 CFR 460 Preamble Discussion/Federal Register December 2006);

- **Effectiveness and Safety of Direct and Contracted Services Delivered to Participants.** The effectiveness and safety of the PACE services provided by the PACE organizations staff or contracted services must be evaluated, to include competency of clinical staff, promptness of service delivery, and achievement of treatment goals and measurable outcomes.

For participants to experience the outcomes that the PACE benefit is intended to achieve, staff must demonstrate skills and competencies necessary to facilitate those desired outcomes. The PACE organizations is expected to include data-based, criterion-referenced performance measures of staff skills, to utilize these data to ensure that staff maintains skills and to provide training as new techniques and technologies are introduced and as new staff are hired. Each PACE organizations will be expected to demonstrate that it has a system of appropriate complexity for keeping track of the skills and competencies of the staff and for effectively identifying and addressing staff training needs. These data should be an integral part of the PACE organizations internal QAPI program that provides continuous feedback on staff performance;

- **Non-Clinical Areas.** The types of outcomes in this area include outcomes related to grievances and appeals, transportation services, meals, life safety, and environmental issues.

For example, if a PACE organizations finds a high rate of grievances not resolved, the PACE organizations might target its activities to improve the grievance process.

Furthermore, CMS requires that the PACE organizations ensure the accuracy, integrity, and completeness of all data used for outcome monitoring. A data-driven QAPI program must be based on accurate data. The regulations require that PACE organizations set up mechanisms to check for the accuracy, timely collection, and completeness of all data. As such, CMS would expect to see a formal data integrity training program and competency evaluation for all staff responsible for collecting or analyzing data.

[42 CFR §§ 460.130, 460.132(c)(2), 460.134(a) and (d); 71 FR 71304 through 71306 (Dec. 8, 2006)]

### **10.2.3 Internal QAPI Activities**

PACE organizations must use a set of outcome measures to identify areas of good or problematic performance and take actions targeted at maintaining or improving care based on these outcome measures. CMS expects PACE organizations to use the most current clinical practice guidelines and professional standards in the development of outcome measures applicable to the care of PACE participants. Continuous improvement is only possible through identification and use of current information, techniques, and practices. CMS also expects the PACE organization will utilize the current clinical and professional standards as a routine part of its daily operations.. A PACE organization must ensure that all IDT members, PACE staff, and contract providers are involved in the development and implementation of QAPI activities and are aware of the results of these activities. As such, the PACE organization must:

- Establish and maintain a health information system that collects, analyzes, integrates, and reports data to measure the organization's performance, including outcomes of care furnished to participants. Involved staff in each stage of data collection and analysis must be sufficiently trained in data integrity concepts and practices to assure the soundness and applicability of the data the PACE organization will act upon;
- Use a set of outcome measures to identify areas of good or problematic performance;
- Prioritize performance improvement activities based on prevalence and severity of identified problems, and give priority to activities that improve clinical outcomes;
- Develop and implement plans of action to improve or sustain quality services or care;
- Immediately correct an identified problem that directly or potentially threatens the health or safety of participants;
- Document and disseminate QAPI results to staff and contractors; and

- Incorporate improvements into standard practice for the delivery of care and periodically track performance to ensure that any performance improvements are sustained over time.

Furthermore, the PACE organization must meet minimum levels of performance on standardized quality measures which are specified in the PACE Program Agreement. Currently, CMS requires all PACE organizations to achieve at least an 80 percent flu immunization rate for their PACE participants. If a PO fails substantially to meet these specified requirements, the continuation of the PACE program agreement may be conditional on the execution of a CAP, or alternatively, some or all further payments for PACE program services may be withheld until the deficiencies have been corrected.

By virtue of being a full-service program targeting the vulnerable frail elderly, PACE leaders face unique challenges. An effective QAPI program requires continuous surveillance by all stakeholders (employed and contracted staff, caregivers, and participants) of the range of PACE services. CMS believes the designation of a dedicated QAPI coordinator is imperative to conduct continuous performance improvement activities that inform the PACE organization leadership ultimately responsible for care delivery including, but not limited to, ambulatory, home health, adult daycare, long-term, acute, emergency, and restorative services. Within these domains of care, leaders oversee multiple disciplines internally – medical, nursing, social, mental health, recreation therapy, dietary, restorative therapies, transportation – as well as specialized services in the community.

CMS requires the PACE organization to identify the Medical Director as the person and position responsible for the oversight of the QAPI program. Furthermore, the medical director has oversight responsibility for patient outcomes, assures data completeness, plan development, performance of activities, and outcome evaluations for plan effectiveness.

A PACE organization must designate an individual to be the QAPI coordinator, whose function is to coordinate and oversee the implementation of quality assessment and performance improvement activities. The QAPI coordinator would be responsible for day-to-day quality issues, collecting data, analyzing data, detecting trends, coordinating IDT members, PACE staff, and contract providers in planning QAPI activities, disseminating reports on activities to them, and compiling comments related to participant/caregiver satisfaction and concerns. The QAPI coordinator must encourage a PACE participant and his or her caregivers to be involved in QAPI activities, including providing information about their satisfaction with services.

[42 CFR §§ 460.134, 460.136, and 460.202(a); Level Two Guidance, October 2010]

#### **10.2.4 QAPI Committee**

A PACE organization develop a committee(s) with community input to 1) evaluate data collected pertaining to quality outcome measures, 2) address the implementation of and results from the QAPI plan, and 3) provide input related to ethical decision-making including end-of-life issues and implementation of the Patient Self-Determination Act. Through this committee(s), the PACE organization will be able to receive guidance regarding its QAPI program and the ethical issues faced by PACE organizations.

[42 CFR § 460.138]

### **10.3 Additional Quality Assessment Activities**

An essential component of an effective quality improvement program is risk assessment and management. Risk management entails identifying and systematically reducing potential risks to the safety of PACE participants and the healthcare environment. Risk assessment ideally is conducted prospectively to prevent occurrences that result in adverse health outcomes to participants or staff, or harm to the organization's physical plant/equipment or fiscal status. In reality, risk assessment is most often conducted in response to an event that results in medical, psychosocial, cognitive, or functional harm to a participant or staff. Every person employed or contracted by the PACE organization has responsibility for risk assessment and management.

CMS and State Administering Agencies partner with PACE organizations to enhance internal quality assurance and risk management activities. A PACE organization must meet external quality assessment and reporting requirements, as specified by CMS or the State Administering Agency regarding participant health outcomes data. Through the external reporting requirements, CMS and the State Administering Agency monitor the PACE organization's quality of care and risk reduction efforts. External monitoring activities refer to both the submission of the aggregated monitoring data elements via the PACE monitoring module of the Health Plan Management System (HPMS) (Level One Reporting) and the reporting of events resulting in significant harm to participants, or negative national or regional notoriety related to the PACE program (Level Two Reporting) (CMS, PACE Level Two External Reporting Guidance, October, 2010 (effective 01/04/2011)). This manual and the PACE Level Two External Reporting Guidance (the "Level Two Guidance") clarify the Level Two reporting events that must be expeditiously reported to CMS.

[42 CFR § 460.140; Level Two Guidance, October 2010]

#### **10.3.1 External Reporting Requirements**

This Manual and the Level Two Guidance provide an overview of requirements of PACE organizations to report both aggregate and individual-level data to CMS and State Administering Agencies for their use in monitoring PACE organizations' performance.

PACE requirements include Level One and Level Two Reporting, Health Outcomes Survey-Modified (HOS-M) participation and additional reporting to other Federal and State health authorities as required.

The Level Two Guidance replaces the Sentinel Events Reporting Policy issued by CMS in 2004. In so doing, CMS is discontinuing use of the term “sentinel event” and adopting an external reporting paradigm that distinguishes between Level One and Level Two Reporting Requirements as described below.

[42 CFR §§ 460.140 and 460.202(b), Level Two Guidance, October 2010]

### **10.3.1.1 Level One Reporting Requirements**

Level One Reporting Requirements refers to those data elements for monitoring that are regularly reported by PACE organizations via the Health Plan Management System (HPMS) PACE monitoring module. These monitoring elements are detailed in the HPMS PACE User’s Guide, Fall 2005 (<https://www.cms.gov/PACE/Downloads/hpmsmanual.pdf>) and include:

- Routine Immunizations;
- Grievances and Appeals;
- Enrollments;
- Disenrollments;
- Prospective Enrollees;
- Readmissions;
- Emergency (Unscheduled) Care;
- Unusual Incidents; and,
- Deaths.

The HPMS database is regularly monitored by staff in the CMS Regional Office (RO) and State Administering Agency (SAA).

Data reported in response to the Level One Reporting Requirement are used by PACE organizations to identify opportunities for quality improvement. For example, based on their review of Level One data reported in HPMS, PACE organization’s may:

- Conduct a QAPI activity using a standardized methodology (e.g., Plan, Do, Check, Act known as PDCA) if a policy or system problem is identified;
- Institute QAPI-driven change in policies, procedures, systems, or training as appropriate;
- Evaluate the effectiveness of the intervention;
- Track and trend for sustainable improvement;
- Reevaluate until improvement is sustained;
- Document for review during CMS/State Administering Agency audit as evidence of a performance improvement activity;
- Report findings at least annually to oversight committees including the PACE organization's governing board.

[HPMS PACE User's Guide, Fall 2005, Level Two Guidance, October 2010]

### **10.3.1.2 Level Two Reporting and Reporting Thresholds**

When unusual incidents meet specified reporting thresholds, PACE organizations are required to report them on a timely basis as Level Two Reporting Incidents to CMS Central Office and Regional Offices and the State Administering Agency. Level Two incidents require internal investigation and analysis of the occurrence by the PACE organization with the goal of identifying system(s) failures and improvement opportunities.

For example, Level Two reportable incidents may include:

- **Deaths** related to suicide or homicide (known or suspected), Unexpected and with active coroner investigation;
- **Falls** resulting in death or in injury requiring hospitalization of five days or more, or resulting in injury for which the determination is made within 48 hours of the fall that permanent loss of function is expected;
- **Infectious Disease Outbreak** that meet the threshold of three or more cases (or the respective State standard if more stringent) linked to the same infectious agent within the same time frame;
- **Pressure Ulcer** acquired while enrolled in the PACE program;

- **Traumatic Injuries** which result in death or hospitalization of five days or more, or result in injury for which the determination is made within 48 hours of the injury that permanent loss of function is expected.

For a specific listing of reportable incidents and thresholds, please refer to the Level Two External Reporting Guidance, October 2010.

#### **10.3.1.2.1 Reporting Requirements of Level Two Incidents**

When an incident meets a Level Two reporting threshold, the PACE organization must complete the following three steps:

1. Within 48 hours of determining the threshold for Level Two reporting has been met, notify CMS via e-mail at the dedicated PACE mailbox [PACE@cms.hhs.gov](mailto:PACE@cms.hhs.gov) and copy the State Administering Agency and the Regional Office.

#### **Examples:**

- If an incident results in a participant's death, the incident must be reported within 48 hours of the participant's death;
- If an incident results in a hospitalization of five days or more, the incident must be reported within 48 hours of the 5th day of the hospital admission;
- In cases where a determination is made within 48 hours that permanent loss of function is expected, reporting must take place within 48 hours of such determination.

Email notification must provide:

- Subject Line: "PACE Level Two Report";
- The age and gender of participant involved;
- Identify the date and type of unusual incident, and the threshold for reporting, e.g., 87-year-old female participant experienced a fall on DATE which resulted in a hospitalization of five days or more;
- PACE organization name and reporting staff contact information.

If the PACE organization is unsure if a Level Two reporting threshold has been met, the PACE organization will consult with its CMS Regional Office Account Manager by telephone. The PACE organization's contact with the CMS Regional Office Account

Manager must be made within 24 hours (or next business day) of determination that Level Two reporting may be required.

2. The PACE organization must undertake an internal investigation of the incident. The investigation must be initiated within 24 hours of reporting the incident to CMS and the State Administering Agency, and must be concluded within 30 days of reporting the incident. If the internal investigation cannot be completed within 30 days, then prior to the 30-day deadline, the organization must notify CMS by sending an email to [PACE@cms.hhs.gov](mailto:PACE@cms.hhs.gov) with a copy to the State Administering Agency and the CMS Regional Office. The notification must describe the circumstances preventing completion of the investigation within the 30-day time period and provide information on when the investigation will be completed.

In general, it is expected that the PACE organization's investigation will include a root cause analysis as described below. There are instances, however, when PACE organization staff may feel that a root cause analysis will not yield programmatic improvement information. If this is the case, PACE organization is to consult promptly by telephone with its CMS Regional Office Account Manager.

It is important to document all participant-specific events in the PACE medical record, particularly if they result in injury or require a treatment or a change in the care plan. Documentation should include a statement of the event, an assessment, a diagnosis (if appropriate), any follow up plans and participant progress. However, any specific details that relate to the investigation of the event (e.g, what were the contributing factors, was care inconsistent with policy, any concerns of quality of care, etc.) do not need to be included in the medical record. All such documentation should be kept separately in a Quality Assurance file.

3. Notify CMS via [PACE@cms.hhs.gov](mailto:PACE@cms.hhs.gov) with a copy to the State Administering Agency and CMS Regional Office when the internal investigation is completed. CMS will schedule a conference call within 30 days of this notification to discuss the organization's internal investigation, subject to the availability of key individuals from all entities. Any additional follow-up required subsequent to the call will be coordinated by the PACE organization, CMS RO and the SAA.

[Level Two Guidance, October 2010][ <http://www.cms.gov/pace/>]

#### **10.3.1.2.2 Process for Conducting Root Cause Analysis**

A root cause analysis must be completed for events for which the PACE organization's staff, or PACE organization staff in consultation with the CMS Regional Office, determines the identified event is sufficiently serious that an in-depth understanding of how it could occur is essential, and/or multiple fail-safe measures are required as part of the organization's improvement plan. As described above, PACE organizations are to consult with their CMS

Regional Office Account Manager in cases where the PACE organization believes a root cause analysis is not necessary.

There are many print and web-based resources to guide PACE personnel in conducting a root cause analysis. Several essential elements are outlined below:

- **Describe the details of what happened.** The description will help define the underlying problem. Who was involved? What were the circumstances of the event? When did it occur? Where did it happen?
- **Identify the immediate factors that contributed to the event.** This step enables the team to gather evidence. CMS recommends that the team ask why the event occurred and what relationships were associated with the defined problem. Specify factors that, if removed or changed, could prevent a recurrence;
  - **What were the human factors?** (Staffing levels, knowledge, training, competency, fatigue, distractions, etc.);
  - **Was the risk identified, adequately assessed, and a reduction strategy put in place prior to the incident?** (Timely, comprehensive, documented, communicated to pertinent persons, etc.);
  - **What were the equipment-related factors?** (Maintenance, mechanical failure, age, operational history, etc.);
  - **What were the environmental factors?** (Lighting, noise, clutter, cleanliness, temperature, inspections, security, etc.);
  - **What were the communication factors?** (Adequate tools in place, in-service training, documented policies and procedures, reciprocal flow from/to management, information readily available, technical support, etc.);
- **Develop a risk reduction strategy for each identified problem that differentiates effective solutions that meet team goals:**
  - Discuss the rationale if the team determines that no action should be taken;
  - Develop and implement a corrective action if the team determines that a policy, procedure, system, training, or process should be improved;
  - Design a performance measure to assess if the team's corrective action is effective and sustained over time;
  - Define the period during which progress will be monitored for improvement;

- **Evaluate the effectiveness of corrective action:**
  - Assess the improvement in performance;
  - Revise the action plan accordingly.

### **10.3.1.2.3 Format for Level Two PACE Organization Conference Call Case Presentation**

When the PACE organization has completed its internal investigation of the incident meeting the threshold for Level Two Reporting, the PACE organization must notify CMS via [PACE@cms.hhs.gov](mailto:PACE@cms.hhs.gov) with a copy to the State Administering Agency and CMS Regional Office. The PACE organization must prepare a case presentation for discussion on the call. When preparing the case presentation, the PACE organization will include the following information in its discussion:

- Summary of the care history;
- Age and gender of participant;
- Date of enrollment into the program;
- Significant diagnoses;
- Participant's degree of involvement in PACE program;
- IDT team's main concerns related to participant prior to event;
- Summary of the event;
- Precipitating/contributing factors;
- Participant's involvement/actions surrounding the event;
- Immediate actions taken;
- Participant's status;
- Working relationship with contracted facility, contracted services (if applicable);
- Compliance with organization's established policies and procedures;

- Identification of risk points and their potential contribution to the event;
- As appropriate, proposed improvements in policies, training, procedures, systems, processes, physical plant, staffing levels, etc. to reduce future risks.

For a specific listing of reportable incidents and case scenarios, please refer to CMS, PACE Level Two External Reporting Guidance, October, 2010 (effective 01/04/2011).

### **10.3.1.3 Health Outcomes Survey – Modified (HOS-M)**

The Medicare Health Outcomes Survey-Modified (HOS-M) was fielded for the first time in the spring of 2005. Originally entitled the Program of All-Inclusive Care for the Elderly (PACE) Health Survey, the HOS-M is administered to vulnerable Medicare beneficiaries at greatest risk for poor health outcomes. These beneficiaries are enrolled in PACE organizations. All PACE plans with Medicare contracts in effect on or before January 1 of the preceding year are required by CMS to administer the HOS-M during the current reporting year (e.g., January 1, 2009 for the 2010 HOS-M administration).

The HOS-M is a modified version of the Medicare HOS that is administered by CMS. Similar to the HOS, the HOS-M design is based on a randomly selected sample of individuals from each participating PACE organization. The HOS-M is a cross-sectional survey, measuring the physical and mental health functioning of beneficiaries at a single point in time. This differs from the HOS, which has a follow-up component.

One of the main goals of the HOS-M is to assess annually the frailty of the population in these PACE organizations in order to adjust plan payment rates. Initial eligibility for payment purposes is based on community-residing members who do not have end-stage renal disease (ESRD) and are 55 or over.

#### **10.3.1.3.1 Medicare HOS-M Sampling**

A random sample of Medicare beneficiaries is drawn annually from each participating PACE organization and surveyed in the spring. Participants are defined as eligible for the HOS-M if they are enrolled in a participating HOS-M plan, reside in the community, do not have End Stage Renal Disease (ESRD), and are age 55 and over. Members are randomly selected for HOS-M if the plan has a population of at least 1,400 members. All eligible participants are included in the sample for PACE organizations with populations of less than 1,400.

#### **10.3.1.3.2 HOS-M Instrument**

The Medicare HOS-M contains the following core components:

- The Veterans RAND 12 Item Health Survey (VR-12);

- Activity of Daily Living (ADL) items.

The HOS-M instrument is a shorter, modified version of the Medicare Health Outcomes Survey and contains 6 ADL items as the core items used to calculate the frailty adjustment factor for payment purposes. The survey also includes 12 physical and mental health status questions from the VR-12. In addition, the HOS-M includes questions about the following: lifting or carrying objects as heavy as 10 pounds; walking a quarter mile; health or physical problems interfering with daily activities, receiving help with ADLs; physical and emotional health compared to one year ago; memory loss; urinary incontinence; and a question on whether the survey was self-completed or completed by a proxy. If the participant received assistance completing the survey, the respondent was asked information about the proxy respondent.

#### **10.3.1.3.3 Dissemination of HOS-M Results to Plans**

After each yearly administration of the Medicare HOS-M, a PACE organization-specific report is produced and is available for each PACE organization participating in the survey. The HOS-M report presents physical and mental component summary scores, ADL items, and selected health status measures, for the frail, elderly Medicare beneficiaries for each organization compared to the entire HOS-M sample.

The corresponding beneficiary level data for a report are disseminated to participating PACE organizations. In addition to the data files, each PACE organization is provided with a Data User's Guide that describes the Medicare HOS-M file specifications and the appropriate use of Medicare HOS-M data.

All distribution of HOS-M reports occurs electronically to participating PACE organizations through CMS' Health Plan Management System (HPMS) in the fall of each year. Plans are alerted of report and data availability through HPMS and may request data from HOS Technical Support ([hos@aqzio.sdps.org](mailto:hos@aqzio.sdps.org) or toll free 888-880-0077).

#### **10.3.1.3.4 HOS-M Program or Policy Questions**

Any program or policy questions concerning the HOS-M may be directed to [hos@cms.hhs.gov](mailto:hos@cms.hhs.gov). Additional information on both the HOS and HOS-M programs is available at [www.hosonline.org](http://www.hosonline.org).

#### **10.3.1.4. Additional Required Reporting**

In addition to required CMS and State Administering Agency reporting, certain unusual incidents are regulated and must also be reported to other Federal and State agencies consistent with these agencies' requirements.

For example:

- If a PACE organization suspects an incident of elder abuse, it must notify the appropriate State agency with oversight for elder affairs;
- PACE organizations experiencing an incident related to equipment failure or administration of medication to a participant that results in a serious adverse participant outcome are strongly encouraged to report the incident to the Federal Food and Drug Administration (through MedWatch on the FDA website);

PACE organizations experiencing an infectious disease outbreak (three or more participants affected by the same agent in the same time period) caused by an agent, such as Hepatitis A, must report the outbreak to the State public health agency with responsibility. In some situations, the State agency may instruct the PACE organization to report concurrently to the Centers for Disease Control and Prevention. The PACE organization must make the notification(s) and take any prescribed actions within the prescribed time frame to comply with applicable statutory or regulatory requirements. Specific requirements can be found on the respective Federal or State agencies' websites.

## Chapter 11 - PACE Grievances and Appeals

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### Table of Contents

<a href="#"><u>11.1 Grievances</u></a>	117
<a href="#"><u>11.2 Appeals</u></a>	118
<a href="#"><u>11.2.1 Internal Processes</u></a>	118
<a href="#"><u>11.2.1.1 Standard</u></a>	118
<a href="#"><u>11.2.1.2 Expedited Appeals</u></a>	119
<a href="#"><u>11.2.1.3 Additional Appeal Rights Under Medicare or Medicaid</u></a>	120
<a href="#"><u>11.2.1.3.1 Medicare</u></a>	120
<a href="#"><u>11.2.1.3.2 Medicaid</u></a>	120

## 11.1 Grievances [42 CFR §460.120]

**A grievance is defined as a complaint, either written or oral, expressing dissatisfaction with the service delivery or the quality of care furnished.**

The PACE organization must have a formal written process to evaluate and resolve grievances, whether medical or non-medical in nature, by PACE participants, their family members or representatives. All personnel (employees and contractors) who have contact with participants should be aware of and understand the basic procedures for receiving and documenting grievances in order to initiate the appropriate process for resolving participant concerns. All participants must be informed of the grievance process in writing upon enrollment into the PACE program and at least annually thereafter.

The PACE organization's grievance process, at a minimum, must include written procedures for the following:

- How a participant files a grievance;
- Documentation of a participant's grievance;
- Response to and resolution of the grievance in a timely manner;
- Maintenance of the participant's confidentiality throughout the grievance process and thereafter.

The PACE organization's internal procedures should assure that every grievance is handled in a uniform manner and that there is communication among different individuals who are responsible for reviewing or resolving grievances. In addition, the PACE organization must maintain appropriate documentation so the information can be utilized in the organization's QAPI program.

The PACE organization must discuss with and provide to the participant in writing the specific steps, including timeframes for response, that will be taken to resolve the participant's grievance. It is expected that each PACE organization have a template prepared to acknowledge a beneficiary grievance with timeframes and additional information on the process, for example, a participant grievance form to acknowledge the grievance and a letter of resolution informing the participant of the grievance outcome. The PACE organization must continue providing all required care to the enrolled participant throughout the grievance process. The PACE organization must maintain, aggregate and analyze the information on the grievance process. This information must be utilized as part of the organization's internal QAPI program. Through analyzing the filed grievances there may be an opportunity for process improvement, which could lead to improved quality of care for the participants.

[42 CFR § 460.120; 71 FR 71300 (Dec. 8, 2006)]

## **11.2 Appeals [42 CFR § 460.122]**

**An appeal is defined as a participant's action taken with respect to the PACE organization's non-coverage of, or nonpayment for a service, including denials, reductions, or termination of services.**

The PACE organization must have a formal, written appeals process including timeframes for response to address non-coverage or nonpayment of a service. All participants must be provided written information regarding the appeals process upon enrollment, at least annually thereafter, and whenever the IDT denies a request for services or payment. It is expected that each PACE organization have a template prepared to assist the participant in filing an appeal; a letter to acknowledge that a participant has appealed with the required timeframes and additional information on the process; and a notice of action providing the appeal outcome and information on the next level of appeal.

The information on appeals proceedings will be maintained, aggregated and analyzed by the organization. This process will be utilized as part of the organization's internal QAPI program. Through analyzing the filed appeals, there may be an opportunity for process improvement, which could lead to improved quality of care for the participants.

[42 CFR § 460.122(a), (b), and (i); 71 FR 71301 (Dec. 8, 2006)]

### **11.2.1 Internal Processes**

#### **11.2.1.1 Standard**

The PACE organization internal appeals process, at a minimum, must include written procedures for:

- Timely preparation and processing of written denials of coverage or payment;
- Filing a participant's appeal;
- Documenting the participant's appeal;
- Appointing an appropriately credentialed and impartial third party who was not involved in the original decision and who does not have a stake in the outcome of the appeal to review the participant's appeal;
- Responding to and resolving the participant's appeals as expeditiously as the participant's health condition requires, but no later than 30 calendar days after the PACE organization receives an appeal; and

- Maintaining confidentiality of participant appeals.

The PACE organization must give all parties involved in the appeal appropriate written notification and a reasonable opportunity to present evidence related to the dispute in person as well as in writing.

The PACE organization must continue to furnish care to the participant during the appeal process. Specifically, during the appeals process, the PACE organization must meet the following requirements:

- For a Medicaid participant, continue to furnish the disputed services until issuance of the final determination if the following conditions are met: (1) the PACE organization is proposing to terminate or reduce services currently being furnished to the participant; and (2) the participant requests continuation with the understanding that he or she may be liable for the costs of the contested services if the determination is not made in his or her favor.
- Continue to furnish to the participant all other required services as specified in subpart F of part 460.

[42 CFR § 460.122(c), (d), and (e)]

### **11.2.1.2 Expedited Appeals**

In addition to the standard appeals process, the PACE organization must have an expedited appeals process in place for situations in which the participant believes that if the service is in dispute not furnished, his or her life, health, or ability to regain or maintain maximum function would be seriously jeopardized.

The PACE organization must respond to the appeal as expeditiously as the participant's health condition requires, but no later than 72 hours after it receives the appeal. The 72-hour timeframe may be extended by up to 14 calendar days if the participant requests the extension or the PACE organization justifies to the State Administering Agency the need for additional information and how the delay is in the interest of the participant.

The PACE organization must take appropriate action to furnish the disputed service as expeditiously as the health condition of the participant requires if, on appeal, a determination is made in favor of the participant.

The PACE organization is required to notify CMS, the State Administering Agency, and the participant of its determination that is wholly or partially adverse to a participant at the time the decision is made. CMS notification may be accomplished through HPMS Data Element for monitoring reporting.

[42 CFR § 460.122(f), (h), and (g)]

### **11.2.1.3 Additional Appeal Rights Under Medicare or Medicaid [42 CFR § 460.124]**

The external appeals process provides participants with an appropriate external review depending on their Medicare and Medicaid status. Medicare beneficiaries have access to the Medicare external appeals route through the Independent Review Entity (IRE) that contracts with CMS to resolve Medicare Advantage appeals, while Medicaid eligible individuals have access to the State Fair Hearing process. In those cases where participants are covered only under one program (Medicare or Medicaid), only the applicable appeals process would apply. PACE participants who are dually eligible for both Medicare and Medicaid have the choice of either process, however they may only choose one route by which to exercise their external appeal rights. Allowing dually eligible participants to choose to pursue an appeal through either the Medicare's IRE or Medicaid's State Fair Hearing processes eliminates the possibility of conflicting determinations. Therefore, all PACE participants have one route by which to exercise their external appeal rights. A PACE organization must inform a participant in writing of his or her appeal rights under Medicare or Medicaid managed care, or both, assist the participant in choosing which to pursue if both are applicable, and forward the appeal to the appropriate external entity .

The PACE organization must continue to furnish the non-disputed services to the participant during the appeal process, because sections 1894(a)(1)(B)(i) and 1934(a)(1)(B)(i) of the Act requires that participants receive benefits solely through the PACE organization and, as explained in 42 CFR § 460.98(a), the required services for a participant are those services identified in their plan of care.

[42 CFR § 460.124; 71 FR 71303 (Dec. 8, 2006)]

#### **11.2.1.3.1 Medicare**

Information on the Medicare IRE process is available online at <http://www.medicareappeal.com>.

Although Medicare does not have an external appeals process that permits challenges of disenrollment determinations, participants may use their State's external appeals processes even if they are a Medicare beneficiary only.

[71 FR 71303, 71312, and 71317 (Dec. 8, 2006)]

#### **11.2.1.3.2 Medicaid**

Information regarding the State Fair Hearing process can be obtained from the State Administering Agency. States can determine whether the participant can bypass the internal appeals process and go directly to the State Fair Hearing process.

The PACE organization must continue to furnish disputed services to Medicaid participants until the appeal is complete.

If the decision is unfavorable to the participant, the participant would be responsible for the cost of the disputed service.

The PACE organization must be sensitive to the State Fair Hearing time constraints to ensure that the participants' rights to access the State Fair Hearing are not negated by failure to meet the State timeframes.

[71 FR 71302 and 71304 (Dec. 8, 2006)]

## Chapter 12 - PACE Medical Records Documentation

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### Table of Contents

<a href="#"><u>12.1 Medical Records</u></a>	123
<a href="#"><u>12.1.1 Requirements</u></a>	123
<a href="#"><u>12.1.2 Minimal Content of Medical Records</u></a>	123
<a href="#"><u>12.1.3 Medical Record Availability during Termination</u></a>	124
<a href="#"><u>12.1.4 Enrollment Agreement Information</u></a>	124
<a href="#"><u>12.1.5 Documentation of Disruptive or Threatening Behavior for Involuntary Disenrollment</u></a>	124
<a href="#"><u>12.2 Maintenance of Records and Reporting of Data</u></a>	125
<a href="#"><u>12.3 Safeguarding Medical Records</u></a>	125
<a href="#"><u>12.4 Retention of Records</u></a>	126
<a href="#"><u>12.5 HIPAA Privacy</u></a>	126
<a href="#"><u>12.6 Electronic Record Management (EMR) Guidance</u></a>	127

## **12.1 Medical Records**

### **12.1.1 Requirements**

A PACE organization must maintain a single, comprehensive medical record for each participant, in accordance with accepted professional standards. The records may be totally manual, partially manual and electronic, and/or electronic.

The medical record for each participant must meet the following requirements:

- Be complete;
- Accurately documented;
- Readily accessible;
- Systematically organized;
- Available to all staff;
- Maintained and housed at the PACE center where the participant receives services.

[42 CFR § 460.210(a)]

### **12.1.2 Minimal Content of Medical Records**

The medical record must contain the following:

- Appropriate identifying information;
- Documentation of all services furnished, including the following:
  - A summary of emergency care and other inpatient or long-term care services;
  - Services furnished by employees of the PACE center;
  - Services furnished by contractors and their reports;
- Interdisciplinary assessments, reassessments, plans of care treatment, and progress notes that include the participant's response to treatment;
- Laboratory, radiological and other test reports;

- Medication records;
- Hospital discharge summaries, if applicable;
- Reports of contact with informal support (for example, caregiver, legal guardian, or next of kin);
- Enrollment Agreement;
- Physician orders;
- Discharge summary and disenrollment justification, if applicable;
- Advance directives, if applicable;
- A signed release permitting disclosure of personal information.

The actual incident report is not a required element of the participant medical record. However, a narrative description of the care rendered during and subsequent to the incident is required. This narrative description should be documented in the progress notes of the IDT specialist(s) rendering care. If the incident results in a significant change in health status, the changes in the problem, interventions, measurable outcomes, time lines for monitoring and evaluation, and responsible person(s) performing the intervention should be updated in the individual's care plan.

[42 CFR § 460.210(b), (c), and (d); 71 FR 71326 through 71327 (Dec. 8, 2006)]

### **12.1.3 Medical Record Availability during Termination**

An entity whose PACE Program Agreement is in the process of being terminated must provide assistance to each participant in obtaining necessary transitional care through appropriate referrals and making the participants' medical records available to the new providers in a timely manner to ensure the continuity of care for the participant.

[42 CFR § 460.52]

### **12.1.4 Enrollment Agreement Information**

The medical record should have the following information from the enrollment agreement:

- Signed and dated releases have been obtained;
- The legal guardians/representatives have also signed released documents;

- Confirmation that CMS and the State Administering Agency has received of copy the signed enrollment agreement.

### **12.1.5 Documentation of Disruptive or Threatening Behavior for Involuntary Disenrollment**

If a PACE organization proposes to disenroll a participant who is disruptive or threatening, the organization must document the following information in the participant's medical record:

- The reasons for proposing to disenroll the participant;
- All efforts to remedy the situation.

[42 CFR § 460.164(c)]

## **12.2 Maintenance of Records and Reporting of Data**

A PACE organization must allow CMS and the State Administering Agency access to data and records, including, but not limited to, participant health outcomes data, financial books and records, medical records, and personnel records. In addition, the PACE organization must maintain complete records and relevant information in an accurate and timely manner. The PACE organization must grant each participant timely access, upon request, to review and copy his or her own medical records and to request amendments to those records and abide by all Federal and State laws regarding confidentiality and disclosure for mental health records, medical records and other personal health information. PACE organizations must provide advance notice to participants if they intend to charge for copies of records.

[42 CFR § 460.200(b) and (e)(2) through (4)]

## **12.3 Safeguarding Medical Records**

A PACE organization must establish written policies and implement procedures to safeguarding all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration. These policies and procedures must include the following elements:

- Safeguard the privacy of any information that identifies a particular participant. Information from, or copies of, records may be released only to authorized individuals. Original medical records are released only in accordance with Federal or
- Maintain complete records and relevant information in an accurate and timely manner;

- Grant each participant timely access, upon request, to review and copy his or her own medical records and to request amendments to those records; and
- Abide by all Federal and State laws regarding confidentiality and disclose for mental health records, medical records, and other participant health information, including information that qualifies as protected health information.
- Further information is available at <http://www.cms.hhs.gov/HIPAAGenInfo/Downloads/HIPAAALaw.pdf>.

[42 CFR § 460.200]

## 12.4 Retention of Records

A PACE organization must retain records for the longest of the following periods:

- The period of time specified in State law;
- Six years from the last entry date; and
- For medical records of disenrolled participants, six years after the date of disenrollment.

If litigation, a claim, a financial management review, or an audit arising from the operation of the PACE program started before the expiration of the retention period, specified in the prior three bullets, the PACE organization must retain the records until the completion of the litigation, or solution of the claims or audit findings;

The PACE organization must dispose of medical records that are scanned or imaged in accordance with CMS policy as referenced in <http://www.cms.hhs.gov/manuals/downloads/ge101c07.pdf>.

For purposes of Medicare Part D, PACE organizations are required to retain Part D related records for a period of 10 years in accordance with 42 CFR § 423.505(d). At this time CMS recommends that all PACE organizations keep all records (Part D related and general records) for 10 years.

[42 CFR § 460.200(f)]

## 12.5 HIPAA Privacy

A PACE organization must establish written policies and implement procedures to do the following:

- As discussed in section 12.5 above, safeguard the privacy of any information that identifies a particular participant. Information from, or copies of, records may be released only to authorized individuals. Original medical records are released only in accordance with Federal or State laws, court orders, or subpoenas.
- Maintain complete records and relevant information in an accurate and timely manner.
- Grant each participant timely access, upon request, to review and copy his or her own medical records and to request amendments to those records; and
- Abide by all Federal and State laws regarding confidentiality and disclose for mental health records, medical records, and other participant health information, including information that qualifies as protected health information (For example, see [PACE Manual Chapter 2](#) and <http://www.cms.hhs.gov/HIPAAGenInfo/Downloads/HIPAALaw.pdf> for further information on HIPAA).

[42 CFR § 460.200(e)]

## 12.6 Electronic Record Management (EMR) Guidance

At the present time, there is no specific guidance from CMS regarding PACE EMR management. However, there are guidance formats for all providers and programs on the [www.cms.hhs.gov](http://www.cms.hhs.gov) for reference of the new interim rule (45 CFR Part 170 Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology: Interim Final Rule; Federal Register: January 13, 2010 (Volume 75, Number 8))[Rules and Regulations][Page 2013-2047]) at <http://edocket.access.gpo.gov/2010/E9-31216.htm>.

The adopted standards are organized into the following four categories:

- **Vocabulary Standards** (i.e., standardized nomenclatures and code sets used to describe clinical problems and procedures, medications, and allergies);
- **Content Exchange Standards** (i.e., standards used to share clinical information such as clinical summaries, prescriptions, and structured electronic documents);
- **Transport Standards** (i.e., standards used to establish a common, predictable, secure communication protocol between systems); and
- **Privacy and Security Standards** (e.g., authentication, access control, transmission security) which relate to and span across all of the other types of standards.

Use Cases and Requirements for EMR/EHR are available at:

[http://healthit.hhs.gov/portal/server.pt?open=512&objID=1255&parentname=CommunityPage&parentid=6&mode=2&in\\_hi\\_userid=10741&cached=true](http://healthit.hhs.gov/portal/server.pt?open=512&objID=1255&parentname=CommunityPage&parentid=6&mode=2&in_hi_userid=10741&cached=true).

EMR report of standards for Health **Information Security and Privacy Collaboration: Adoption of Standard Policies Collaborative Final Report** is available at:

[http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS\\_0\\_10741\\_872248\\_0\\_0\\_18/ASP\\_2\\_1\\_Final\\_Rpt\\_with\\_app\\_ABCDEHJK.pdf](http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10741_872248_0_0_18/ASP_2_1_Final_Rpt_with_app_ABCDEHJK.pdf).

## Chapter 13 - Payments to PACE Organizations

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### Table of Contents

<a href="#"><u>13.1 Introduction</u></a>	132
<a href="#"><u>13.1.1 General Payment Principles</u></a>	132
<a href="#"><u>13.2 Organization Responsibilities</u></a>	132
<a href="#"><u>13.3 Payment Methodology</u></a>	132
<a href="#"><u>13.3.1 Part A and Part B of Medicare</u></a>	131
<a href="#"><u>13.3.2 Medicare Part D Payment</u></a>	132
<a href="#"><u>13.3.3 Medicaid</u></a>	133
<a href="#"><u>13.3.4 Post-Eligibility Treatment of Income</u></a>	134
<a href="#"><u>13.4 PACE Premiums</u></a>	134
<a href="#"><u>13.4.1 Definition of Premiums</u></a>	135
<a href="#"><u>13.4.2 Categories</u></a>	135
<a href="#"><u>13.4.3 Premiums for Persons Who Are Medicare Eligible</u></a>	135
<a href="#"><u>13.4.3.1 Participant Part B Premiums</u></a>	136
<a href="#"><u>13.4.3.2 Part D</u></a>	136
<a href="#"><u>13.4.4 Premiums for Persons Who Are Medicaid Only</u></a>	137
<a href="#"><u>13.4.5 Premiums for Persons who are Private Pay (without Medicare or Medicaid)</u></a>	137

## **13.1 Introduction**

This chapter gives an overview of the policies and methods CMS follows in determining the amount of payment a PACE organization will receive for coverage of benefits for PACE participants who are enrolled in their plan as provided by 42 CFR § 460.180 of the PACE Regulations.

### **13.1.1 General Payment Principles**

The following basic principles distinguish the PACE financing model:

- Obligation for payments is shared by Medicare, Medicaid, and individuals who do not participate in Medicare and Medicaid;
- Medicare, Medicaid, and private payments for acute, long-term care, and other services are pooled;
- The capitation rates paid by Medicaid are designed to result in cost savings relative to expenditures that would otherwise be paid for a comparable nursing facility-eligible population not enrolled under the PACE program;
- Medicare rates are risk-adjusted based on diagnosis;
- The PACE organization accepts the capitation payment amounts as payment in full from Medicare and Medicaid.

[71 FR 71318 (Dec. 8, 2006)]

## **13.2 PACE Organization Responsibilities**

PACE organizations are paid monthly payments of a capitation amount for each eligible enrolled PACE program participant in the same manner and from the same sources as payments that are made to a Medicare Advantage organization under section 1853 of the Act. Capitation payments will not be paid directly to participants [42 CFR § 460.180].

The PACE organization is required to do the following:

- Verify at time of enrollment whether the participant is dually eligible for Medicare and Medicaid and whether the participant has Medicare Part A and Part B;
- Remind participants that unless they are dually eligible, they will need to continue to pay their Medicare Part A premium, if not free Part B and/or Part D premiums;
- Identify payers that are primary to Medicare;

- Determine the amounts payable by those payers;
- Coordinate benefits to Medicare participants with the benefits of primary payers.

[71 FR 71318 (Dec. 8, 2006), 42 CFR § 460.152(a); 71 FR 71309 (Dec. 8, 2006), and 42 CFR § 460.150)]

### **13.3 Payment Methodology**

#### **13.3.1 Part A and Part B of Medicare**

Section 1894(d)(1) of the Act requires that PACE organizations be paid monthly payments of a capitation amount for each eligible enrolled PACE participant, in the same manner and from the same sources as payments that are made to a Medicare +Choice (now Medicare Advantage) and be adjusted to account for the comparative frailty of PACE enrollees and other factors that the Secretary determines appropriate. Under a PACE agreement, CMS makes a prospective monthly payment to the PACE organization of a capitation amount for each Medicare participant in payment area based on the rate it pays to a Medicare Advantage organization. Medicare Advantage rates mean Part A and Part B rates calculated by CMS for making payment to Medicare Advantage organizations under section 1853(c) of the Act. The individual participant risk score for Medicare Advantage and PACE is calculated using the appropriate CMS–HCC model (community, long-term institutionalized, End-Stage Renal Disease (ESRD) or new enrollee) based on the participant’s status. The risk adjustment is augmented with a frailty adjustor for functionally impaired community residents in PACE using a frailty adjustment on Activities of Daily Living (ADLs), a proxy for functional impairment, and applies only to community-based and short-term institutionalized participants (that is, the frailty adjustment for long-term institutionalized participants is zero). The purpose of the PACE frailty adjustment is to predict the Medicare expenditures of community populations with functional impairments that are unexplained by risk adjustment. Payments of a capitated amount are to be retroactively adjusted to take into account any difference between the actual number of participants and the estimated number of participants to be enrolled in determining the amount of the advance payment. For Medicare participants who require ESRD services, the monthly capitation amount is based on the Medicare Advantage ESRD risk adjustment model.

The risk score is computed for each participant for a given year and applied prospectively. The risk score generally follows the beneficiary for one calendar year. The prior year’s functional impairment data are used to predict the next year’s payment adjustment. Functional data are submitted to CMS, where they are calculated to establish the PACE organization’s frailty score, which is then applied to each participant’s risk adjusted payment. The frailty adjustment approach is applied in conjunction with the CMS–HCC risk adjustment model. The frailty adjustment and factors were initially described in the CY 2004 Advance Notice and Announcement of Medicare Advantage Payment Rates. The CY 2004

Advance Notice and Announcement of Medicare Advantage Payment Rates can be found on the CMS Web site at:

<http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/Downloads/Announcement2004.pdf>.

Separate rates are established for Medicare Part A and Part B. The PACE organization receives payments based on each participant's entitlement to Medicare Part A and Part B. Therefore, if the participant is entitled to Part A benefits, but is not enrolled under Part B, the PACE organization receives only the monthly capitation rates established for Part A. For Medicare Part A-only participants who are also eligible for Medicaid, the State is obligated to pay Medicare Part B premiums under Section 1902(a)(10) of the Act. PACE organizations need to verify, at the time of enrollment, whether the participant is dually eligible for Medicare and Medicaid, and whether the participant has Medicare Part A and Part B.

The monthly capitation payment is a fixed amount, regardless of changes in the participant's health status. It is an all-inclusive payment for Medicare benefits provided to participants. A PACE organization must not seek any additional payment from Medicare. The only additional payment that a PACE organization may collect from, or on behalf of, a Medicare participant for PACE services is: (1) any applicable premium amount; (2) any charge permitted under MSP rules when Medicare is not the primary payer; (3) any payment from the State as specified under the section below on Medicaid, for a participant who is eligible for both Medicare and Medicaid; (4) payment with respect to any applicable spenddown liability under §§ 435.121 and 435.831 and any amount due under the post-eligibility treatment of income process under § 460.184 for a participant who is eligible for both Medicare and Medicaid.

The payment methodology for establishing the monthly capitation rate will be included in the PACE Program Agreement in accordance with the changes to the Medicare Advantage capitation payment methodology. CMS computes this amount so that the total payment level for all participants is less than the projected payment under Medicare for a comparable population not enrolled under a PACE program.

If the actual number of Medicare participants differs from the estimated number of participants on which the amount of the prospective monthly payment was based, CMS adjusts subsequent monthly payments to account for the difference.

[42 CFR § 460.180(a) through (c); 71 FR 71318 through 71319 (Dec. 8, 2006)]

### **13.3.2 Medicare Part D Payment**

In order for PACE organizations to continue to meet the statutory requirement of providing prescription drug coverage to their enrollees, and to ensure that they receive adequate payment for the provision of Part D drugs, beginning January 1, 2006, PACE organizations began to offer qualified prescription drug coverage to their enrollees who are Part D eligible

individuals. The MMA did not impact the manner in which PACE organizations are paid for the provision of outpatient prescription drugs to non-part D eligible PACE participants.

PACE organizations are required to annually submit two Part D bids: one for a Plan Benefit Package (PBP) for dually eligible enrollees and one for a PBP for Medicare-only enrollees. The Part D payment to PACE organizations comprises several pieces, including the direct subsidy, reinsurance payments, and risk sharing. Payments for eligible enrollees of either PBP will include a low-income premium subsidy for basic Part D benefits. Payments for dually eligible enrollees will also include a low income cost sharing subsidy, an additional amount to cover nominal cost sharing amounts (“2% capitation”), and an additional premium payment in situations where the PACE plan’s basic Part D beneficiary premium is greater than the regional low-income premium subsidy amount.

[PACE Program Agreement Appendix M: Medicare and Medicaid Payment Amounts]

### **13.3.3 Medicaid**

Each State that elects PACE as a Medicaid State Plan option must develop a payment amount based on the cost of comparable services for the State’s nursing-facility-eligible population. Generally, the amounts are based on a blend of the cost of nursing home and community-based care for the frail elderly.

Under a PACE Program Agreement, the State Administering Agency makes a prospective monthly payment to the PACE organization of a capitation amount for each Medicaid participant.

The monthly capitation payment amount is negotiated between the PACE organization and the State Administering Agency, and specified in the PACE Program Agreement. The amount represents the following:

- Is less than the amount that would otherwise have been paid under the State plan if the participants were not enrolled under the PACE program;
- Takes into account the comparative frailty of PACE participants;
- Is a fixed amount regardless of changes in the participant’s health status;
- Can be renegotiated on an annual basis.

Under sections 1894(f)(2)(B)(v) and 1934(f)(2)(B)(v) of the Act, the PACE organization must be at full financial risk. The State may not share risk with the PACE organization. The PACE organization must accept the capitation payment amount as payment in full for Medicaid participants and may not bill, charge, collect or receive any other form of payment

from the State Administering Agency or from, or on behalf of the participant, except as follows:

- Payment with respect to any applicable spend down liability under §§ 435.21 and 435.831 and any amounts due under the post-eligibility treatment of income process under 42 CFR § 460.184;
- Medicare payment received from CMS or from other payers in accordance with 42 CFR § 460.180(d);

State procedures for the enrollment and disenrollment of participants in the State's system; including procedures for any adjustment to account for the difference between the estimated number of participants on which the prospective monthly payment was based and the actual number of participants in the month; is included in the PACE Program Agreement.

[42 CFR § 460.182; 71 FR 71321 (Dec. 8, 2006)]

### **13.3.4 Post-Eligibility Treatment of Income**

Section 1934(b)(1)(A)(i) of the Act states that a PACE organization shall provide to eligible individuals, all covered items and services without application of deductibles, copayments, coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid. States are permitted to use post-eligibility treatment of income in the same manner as it is applied for individuals receiving services under a home and community-based services waiver program under Section 1915(c) of the Act. The post-eligibility treatment of income provision reduces the amount of Medicaid payments to a PACE organization by the amount remaining after specified deductions are made from the income of the PACE participant. The income that remains after these deductions are applied is the amount a participant is liable to pay toward the cost of the PACE services.

An argument could be made that sections 1934(b) and (i) of the Act are in conflict since under 1934(i) of the Act, PACE participants may incur limited liability for part of the cost of their services. However, the type of Medicaid participant liability permitted by section 1934(i) of the act is not cost sharing prohibited by section 1934(b)(1)(A)(i) of the Act. Section 1902(a)(17) of the Act permits an individual (or family) who has more income than allowed for Medicaid eligibility to reduce excess income by incurring expenses for medical or remedial care to establish Medicaid eligibility. However, this spenddown process is used in establishing Medicaid eligibility rather than being the type of cost sharing prohibited by section 1934(b)(1)(A)(i) of the Act which refers to deductibles, copayments, coinsurance or other cost sharing beyond participant liabilities related to Medicaid eligibility.

[42 CFR § 460.184; 71 FR 71322 (Dec. 8, 2006)]

## **13.4 PACE Premiums**

### **13.4.1 Definition of Premiums**

The term “premiums” as used in this section does not include spenddown liability under 42 CFR § 435.121 and 42 CFR § 435.831, or post-eligibility treatment of income under 42 CFR § 460.184. This use of the word premiums is narrower than the way the word is used in the Protocol, where a participant’s “share of cost” responsibility under Medicaid is referred to as a type of premium. In addition, PACE organizations may continue to collect any liability due them under Medicaid spend down and post-eligibility processes, but that liability is not a premium.

[71 FR 71322 (Dec. 8, 2006)]

### **13.4.2 Categories**

Based on sections 1894(i) and 1934(j) of the Act, we believe the Congress’ intended to permit individuals with Medicare Part A, Medicare Part B, Medicaid, any combination of the above, or none of the above mentioned benefits to participate in PACE. 42 CFR § 460.150(d) states that a potential participant is not required to be Medicare enrolled or Medicaid eligible.

A participant’s monthly premium responsibility depends upon his or her eligibility under Medicare and Medicaid.

[42 CFR § 460.150(d); 71 FR 71309 (Dec. 8, 2006)]

### **13.4.3 Premiums for Persons Who Are Medicare Eligible**

Nearly all Medicare participants have both Part A and Part B, and the capitation amount that Medicare pays is the sum of the Part A and Part B capitation rates. However, Section 1894(a)(1) of the Act permits a PACE program eligible individual who is entitled to Medicare benefits under Part A or enrolled under Part B to enroll in the PACE program.

For persons who are eligible under only one part of Medicare, the Medicare capitation amount will be only the portion for that part. Such a participant is required to make up the difference through payment of an additional premium amount equal to the missing piece of the Medicare capitation amount. The premiums for Medicare-only participants are as follows:

- For a participant who is entitled to Medicare Part A and enrolled under Medicare Part B, but is not eligible for Medicaid, the premium equals the Medicaid capitation amount;

- For a participant who is entitled to Medicare Part A, but is not enrolled under Part B and is not eligible for Medicaid, the premium equals the Medicaid capitation amount plus the Medicare Part B capitation rate;
- For a participant who is enrolled only under Medicare Part B and is not eligible for Medicaid, the premium equals the Medicaid capitation amount plus the Medicare Part A capitation rate.

No premium may be charged to a participant who is dually eligible for both Medicare and Medicaid or who is only eligible for Medicaid.

[42 CFR § 460.186; 71 FR 71322 (Dec. 8, 2006)]

#### **13.4.3.1 Participant Part B Premiums**

Unless a PACE participant is Medicaid eligible, he or she is responsible for paying the Part B premium. CMS regulations specifically prohibit PACE organizations from offering gifts or payments to induce enrollment. Thus, the payment of Part B premiums by a PACE organization would essentially constitute an inducement for certain individuals (those who pay Part B premiums out of pocket) to enroll in PACE.

Such payment may also violate Section 231(h) of the Health Insurance Portability and Accountability Act of 1996 [Section 1128(A)(5) of the Social Security Act, codified at 42 U.S.C. Section 1320a7a(a)(5)]. That provision imposes civil money penalties on parties who provide inducements to Medicare or Medicaid beneficiaries that they know or should know are likely to influence a beneficiary's choice of a provider, practitioner, or supplier of Medicare or Medicaid items or services. Although the Office of the Inspector General has not issued an advisory opinion on this topic with respect to PACE, the OIG has reviewed similar proposals from Medicare fee-for-service providers and managed care organizations and has found them to be inappropriate.

[42 CFR § 460.82(e)(3)]

#### **13.4.3.2 Part D**

As specified in Sections 1894 and 1934 of the Act, PACE organizations shall provide all medically necessary services including prescription drugs, without any limitation or condition as to amount, duration, or scope and without application of deductibles, copayments, coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid.

PACE program participants who have Medicare only will receive their qualified prescription drug coverage through Medicare Part D and will be responsible for a monthly premium. PACE program participants who have Medicare and also qualify for the State Medicaid

program will be deemed eligible for the Part D Limited-Income Subsidy which will cover their monthly premium for Medicare Part D. As part of the PACE Program Agreement, the PACE organization agrees to calculate and collect beneficiary Part D premiums, to the extent applicable, in accordance with 42 CFR § 423.286 and § 423.293.

#### **13.4.4 Premiums for Persons Who Are Medicaid Only**

No premium may be charged to a participant who is only eligible for Medicaid. For Medicare Part A-only participants who are also eligible for Medicaid, the State is obligated to pay Medicare Part B premiums under Section 1902(a)(10) of the Act.

[71 FR 71318 (Dec. 8, 2006)]

#### **13.4.5 Premiums for Persons who are Private Pay (without Medicare or Medicaid)**

The statute does not specify the premium that may be charged to non-Medicare and non-Medicaid PACE participants. As CMS has indicated in the preamble to the final rule, it is acceptable for a PACE organization to charge the combined Medicare and Medicaid capitation rates as the premium for these individuals.

[71 FR 71309 (Dec. 8, 2006)]

## Chapter 14 - PACE Coordination of Benefits

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### Table of Contents

<a href="#"><u>14.1 Introduction</u></a>	139
<a href="#"><u>14.2 Part C Medicare Secondary Payer Provisions (MSP)</u></a>	139
<a href="#"><u>14.2.1 Basic Rule</u></a>	139
<a href="#"><u>14.2.2 Responsibilities of the PACE Organization</u></a>	139
<a href="#"><u>14.2.3 Charges to the Individual or Entities</u></a>	139
<a href="#"><u>14.2.4 Federal Black Lung Program</u></a>	140
<a href="#"><u>14.3 Medicare Part D Coordination of Benefits (COB)</u></a>	141
<a href="#"><u>14.3.1 Collection of COB Information for Prescription Drug Coverage</u></a>	141
<a href="#"><u>14.3.2 COB Surveys for Prescription Drug Coverage</u></a>	141
<a href="#"><u>14.3.3 Connecting to Systems for Coordination of Benefits</u></a>	142
<a href="#"><u>14.3.3.1 Data from CMS to PACE Part D Sponsors</u></a>	142
<a href="#"><u>14.3.3.2 Data from PACE Part D Sponsors to the COB System</u></a>	143
<a href="#"><u>14.3.4 Tracking of TrOOP</u></a>	144
<a href="#"><u>14.3.4.1 Dual Eligible Beneficiaries</u></a>	144
<a href="#"><u>14.3.4.2 Beneficiaries Eligible for Only Medicare</u></a>	144
<a href="#"><u>14.3.5 Accessing Covered Part D Drugs</u></a>	144
<a href="#"><u>14.3.6 Transferring Data When a Beneficiary Changes Sponsors</u></a>	144
<a href="#"><u>14.3.7 Guidance Regarding PACE Enrollees with Retiree Drug Subsidy</u></a>	145

## **14.1 Introduction**

In 1980, Congress enacted the first of a series of provisions that made Medicare the secondary payer to certain additional primary plans. These provisions are known as the Medicare Secondary Payer (MSP) provisions and are found at Section 1862(b) of the Social Security Act (the Act). These provisions prohibit Medicare from making payment if payment has been made or can reasonably be expected to be made by the following primary plans when certain conditions are satisfied: group health plans, workers' compensation plans, liability insurance, or no-fault insurance (The private insurance industry generally talks about "**Coordination of Benefits**" when assigning responsibility for first and second payment.).

The purpose of the Coordination of Benefits (COB) process is to identify the health benefits available to a Medicare beneficiary and to coordinate the payment process to prevent mistaken payment of Medicare benefits.

## **14.2 Part C Medicare Secondary Payer Provisions (MSP)**

### **14.2.1 Basic Rule**

Medicare does not pay for PACE services to the extent that Medicare is not the primary payer under part 411. A PACE organization may charge or authorize a provider to seek reimbursement for services from a beneficiary or third parties to the extent that Medicare is made a secondary payer under Section 1862(b)(2) of the Act. Section 1860D-2(a)(4) of the MMA extends the Medicare secondary payer (MSP) procedures applicable to Medicare Advantage organizations under Section 1852(a)(4) of the Act and 42 CFR § 422.108 to Part D sponsors and their provision of qualified prescription drug coverage.

[42 CFR § 460.180(d)(1) and (3)]

### **14.2.2 Responsibilities of the PACE Organization**

The PACE organization is required to do the following:

- Identify payers that are primary to Medicare under part 411;
- Determine the amounts payable by those payers;
- Coordinate benefits to Medicare participants with the benefits of primary payers.

[42 CFR § 460.180(d)(2)]

### **14.2.3 Charges to the Individual or Entities**

The PACE organization may charge other individuals or entities for PACE services covered under Medicare for which Medicare is not the primary payer as follows:

- If a Medicare participant receives from a PACE organization covered services that are also covered under State or Federal workers' compensation, any no-fault insurance, any liability insurance policy or plan, including a self-insured plan, group health plan or large group health plan, the PACE organization may charge any of the following:
  - o The insurance carrier, the employer, or any other entity that is liable for payment for the services under part 411; and
  - o The Medicare participant, to the extent that he or she has been paid by the carrier, employer, or entity.

[42 CFR § 460.180(d)(3), (4), and (5)]

#### **14.2.4 Federal Black Lung Program**

As set forth in Section 1862(b)(2)(A)(ii) of the Social Security Act, Medicare payment may not be made if payment has been made or can reasonably be expected to be made under a workmen's compensation law. As further specified in 42 CFR §460.180(d) of the PACE regulation, Medicare does not pay for services to the extent that Medicare is not the primary payer. The PACE organization must ask questions to secure insurance information and identify payers other than PACE and whether PACE is the primary or secondary payer. The beneficiary must be queried about other possible coverage that may be primary to PACE.

The Federal Black Lung Program is a form of workmen's compensation. As such, Medicare does not pay for services covered under the Federal Black Lung Program because the Black Lung program pays for covered services in full. As such, the PACE organization may seek payment from the Federal Black Lung Program on behalf of Black Lung-eligible PACE participants. To the extent that the participant has been paid by the Federal Black Lung Program for services furnished by the PACE organization, the PACE organization may seek payment from the participant. Illnesses or injuries not related to black lung would be covered by the PACE organization.

The PACE organization is required to report all Medicare Secondary Payer (MSP) information to CMS. As outlined in the final "45-Day Notice" for 2010, released on April 6, 2009, there has been a policy change in the way plans are to report the MSP information. The new policy is outlined in the final "45-Day Notice" for 2010, released on April 6. (The Notice may be viewed at: <http://www.cms.hhs.gov/medicareadvtspeccratestats/ad/List.asp>). This change now supersedes the requirement for plans to submit the results of membership survey data to CMS via the new Transaction 85 for the 2010 MSP factor. Plans should ignore the information outlined in the April Release notification sent in January 2010, regarding the new Transaction 85.

Since CMS has already calculated 2009 MSP plan level factors and they are in use, there is no need to submit data on the new transaction 85. Anything submitted will be ignored by the system. The COB process as outlined in the “45-Day Notice” is the process that will be used for 2010 and going forward.

### **14.3 Medicare Part D Coordination of Benefits (COB)**

On December 8, 2003, Congress enacted the MMA of 2003 (PL 108– 173). Several sections of the MMA impact PACE organizations. Most notably, section 101 of the MMA affected the way in which PACE organizations are paid for providing certain outpatient prescription drugs to any Part D eligible participant. As specified in Sections 1894 and 1934 of the Act, PACE organizations shall provide all medically necessary services including prescription drugs, without any limitation or condition as to amount, duration, or scope and without application of deductibles, copayments, coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid.

Prescription drugs provided under Medicare Part D will be covered in the Medicare capitation rates paid to PACE organizations and payment for non-Medicare covered outpatient prescription drugs and prescribed over-the-counter medications covered in the Medicaid capitation rate.

#### **14.3.1 Collection of Coordination of Benefits (COB) Information for Prescription Drug Coverage**

The Part D sponsor must have a system for collecting and updating information from enrollees about their other health insurance, including whether such insurance covers outpatient prescription drugs, and must report that information to the Coordination of Benefits (COB) Contractor (PACE Part D Solicitation; Medicare Prescription Drug Benefit Manual, Chapter 14-Coordination of Benefits).

#### **14.3.2 Coordination of Benefit (COB) Surveys for Prescription Drug Coverage**

As provided in the MMA, beneficiaries are legally obligated to report information about other prescription drug coverage or reimbursement for prescription drug costs that the beneficiaries have or expect to receive; any material misrepresentation of such information by a beneficiary may constitute grounds for termination of coverage from a Part D plan. PACE Part D sponsors must, therefore, regularly survey their participants regarding any other prescription drug coverage they may have and report that information to the Coordination of Benefits contractor so that it can be validated, captured, and maintained for Coordination of Benefit purposes. Anytime a PACE organization receives information concerning a change, this information should be sent electronically to the Coordination of Benefits contractor within 30 days of receipt.

Except as noted, the Coordination of Benefits survey should be performed within 30 days of the date the PACE organization processes a participant's enrollment and annually thereafter. If a participant indicates on his or her enrollment form that there is no other prescription drug coverage, no PACE organization follow-up is required until the annual survey is performed. However, if the enrollee indicates on the enrollment form that he or she in fact has other prescription drug coverage or does not provide any response to those questions, the sponsor must perform the 30-day survey.

The survey should collect from the participant the same information on other payers that Part D sponsors must submit electronically to the Coordination of Benefits contractor. PACE Part D sponsors have the flexibility to design their survey process according to their own needs. PACE Part D sponsors may conduct their survey by telephone, mail, email if available, or in-person. The survey should not require that the participant provide his or her Social Security Number; instead, PACE Part D sponsors should use other identifiers, such as the Member ID. Also, in addition to providing a self-addressed return envelope for mail surveys, sponsors should include on the survey form itself the mailing address to be used for completed surveys in case the envelope is lost or damaged.

A non-response to the survey regarding other prescription drug coverage cannot be interpreted as a negative answer, since effective coordination of benefits with other prescription drug coverage requires that sponsors be aware of any other prescription drug coverage a beneficiary may have. Therefore, PACE Part D sponsors are required to follow up with participants who fail to respond. Follow-up with non-responding participants may be conducted by telephone, mail, email if available, or in person. After unsuccessful attempts to gain a response using one mode, PACE Part D sponsors may find a change to another mode is more productive. Also, if the participant has had drug claims, PACE Part D sponsors may contact the pharmacy to determine if Coordination of Benefits information was captured while the participant was in the pharmacy. PACE Part D sponsors are expected to make a minimum of three attempts to follow up with non-responding participants. At least one of the follow-up efforts must involve the use of a different method of contact. For example, if the initial survey was mailed, at least one of the follow-up attempts must be other than a mailed survey; i.e., must be conducted by telephone, email if available, or in-person.

PACE Part D sponsors also are responsible for sending electronic updates about their participant's other sources of prescription drug coverage to the Coordination of Benefits contractor. Since supplemental payer information is essential for Coordination of Benefits, PACE Part D sponsors should submit this information to the Coordination of Benefits contractor at least monthly.

### **14.3.3 Connecting to Systems for Coordination of Benefits**

#### **14.3.3.1 Data from CMS to PACE Part D Sponsors**

The Coordination of Benefits contractor performs a daily update of information on other coverage to Medicare Beneficiary Database (MBD). PACE Part D sponsors must establish connectivity with CMS systems, which, among other things, allows Part D sponsors to have direct access to other payer status information as often as their business requirements indicate. Every Federal business day, the Coordination of Benefits contractor pushes out updated information to MBD and then CMS sends the Coordination of Benefits file to the PACE Part D sponsors. For more information on receiving Coordination of Benefits files, see the Plan Communications User's Guide (PCUG) available on the CMS Web site. It is incumbent upon Part D sponsors to note any changes to other payer status included in CMS systems and to send that information to the Coordination of Benefits contractor.

#### **14.3.3.2 Data from PACE Part D Sponsors to the COB System**

There is an electronic interface between PACE Part D sponsors and the Coordination of Benefits contractor known as the Electronic Correspondence Referral System (ECRS). ECRS allows PACE Part D sponsors to submit post-enrollment transactions that change or add to currently known Coordination of Benefits information. PACE Part D sponsors may send ECRS transactions in any of three possible ways: 1) by using Network Data Mover (NDM) (a secure file transfer process) to connect to the ECRS Online Application; 2) by using NDM to send an ECRS flat file; or 3) by using a current SFTP connection to send an ECRS flat file. Part D sponsors are updated on the status of these transactions as they move through the Coordination of Benefits systems and informed on the determination made by the Coordination of Benefits contractor on the transactions via a Coordination of Benefits data report/file. Further information on ECRS is contained in the ECRS User Guide available on the CMS Web site.

The data provided by the Coordination of Benefits contractor on supplemental payers and order of payment are generally the best available information for PACE Part D sponsors and pharmacies to act upon. However, it is important to note that PACE Part D sponsors must coordinate benefits with all other payers providing coverage for covered Part D drugs, even if the COB contractor is unaware of some payers who have submitted batched claims after the point-of-sale transaction at a network pharmacy. Although the Coordination of Benefits contractor may be unaware of them, these other payers may submit claims directly to the PACE Part D sponsor or through the TrOOP facilitation contractor, thereby enabling benefit coordination by the Part D sponsor. Once a sponsor becomes aware of these other payers, sponsors must submit this information via ECRS to the Coordination of Benefits contractor.

Sponsors should utilize the electronic interface established with CMS (via the MARx system) to handle plan enrollments, to transmit certain other payer data elements upon enrollment, and to receive daily transmissions of validated Coordination of Benefits information. As new information about other prescription drug coverage is discovered, sponsors should use ECRS to send the information to CMS. Sponsors should not use the enrollment update transaction to communicate this subsequent information.

Beyond the electronic data transfer requirements described above, PACE Part D sponsors must establish procedures for at least weekly file processing. Sponsors are required to not only receive information, but also apply it to their systems.

The PACE Part D sponsor has a detailed claims adjudication process including flow charts, claims management, data capture and claims data retrieval processes.

PACE is a comprehensive, coordinated model of care designed to meet the needs of frail elders. There are several key differences between the way in which PACE organizations provide the Part D benefit and how it is provided by other Part D sponsors. As such, some Part D requirements are waived for PACE organizations. (See Medicare Prescription Drug Benefit Manual, Chapter 14-Coordination of Benefits, Appendix F – Part D Requirements Waived for PACE Organizations).

#### **14.3.4 Tracking of True Out-Of-Pocket (TrOOP) Costs**

##### **14.3.4.1 Dual Eligible Beneficiaries**

CMS fully subsidizes dual-eligible individuals' Part D coverage in PACE organizations. Therefore, consistent with PACE rules, there is no beneficiary out-of-pocket expense, which eliminates the applicability of TrOOP for these beneficiaries.

##### **14.3.4.2 Beneficiaries Eligible for Only Medicare**

PACE beneficiaries who are only Medicare eligible pay a supplemental premium based on the anticipated cost-sharing covered by the PACE plan. As a result, for these beneficiaries TrOOP does not apply.

#### **14.3.5 Accessing Covered Part D Drugs**

PACE Part D sponsors fully coordinate their participants' access to covered Part D drugs, providing prescriptions directly to the participant. As a result, most PACE Part D sponsors are not set up for real-time, on-line prescription drug claims processing and neither have nor report 4Rx data to CMS.

#### **14.3.6 Transferring Data When a Beneficiary Changes Sponsors**

When a beneficiary disenrolls from a PACE organization and re-enrolls in another Part D sponsor at any time during the coverage year, the PACE organization is required to transfer the TrOOP balance (if any) and the gross covered drug costs to the new sponsor of record to permit the correct placement of the beneficiary in the benefit.

Prior to the January 1, 2009, implementation of the automated TrOOP balance transfer (TBT) process, PACE organizations must send the beneficiary's year-to-date TrOOP and gross

covered drug costs, including amounts accumulated during the beneficiary's period of enrollment in the PACE organization plus amounts previously reported to the PACE organization by a prior plan sponsor for months of enrollment during the same coverage year. For beneficiaries who are Medicare and Medicaid dual eligibles, PACE organizations should use the Dual Eligible PACE Plan Beneficiary Accumulated True Out-of-Pocket Cost Calculator to calculate the amount of TrOOP to be reported to the new plan sponsor. The calculator is available on the CMS Web site: <http://www.cms.hhs.gov/apps/troopcalculator/>.

After the January 2009 implementation of the automated TBT process, PACE organizations will no longer be required to forward amounts from any prior plans of enrollment. These amounts will be reported to the new sponsor via the FIR transactions. PACE organizations will be exempt from the automated TBT process; therefore, PACE organizations must continue to use the current manual process to report TrOOP balances and gross covered drug costs for beneficiaries transferring enrollment to the new plan sponsor as reflected on the TRR reporting the disenrollment from the PACE organization. More information may be found in the Medicare Prescription Drug Benefit Manual Chapter 14: Coordination of Benefits <http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter14.pdf>.

CMS will continue to develop guidance to further clarify the applicability of the Coordination of Benefits requirements to the PACE organizations.

#### **14.3.7 Guidance Regarding PACE Enrollees with Retiree Drug Subsidy**

CMS systems will compare PACE Part D enrollment transactions to information CMS has regarding the existence of employer or union sponsored qualified prescription drug coverage for which the beneficiary is also being claimed for the Retiree Drug Subsidy (RDS). If there is a match indicating that the individual may have such other coverage, the PACE Part D enrollment will be conditionally rejected by CMS systems as incomplete. Within 10 calendar days of receipt of the Code 127 conditional rejection, the PACE organization must contact the individual to confirm the individual's intent to enroll and that the individual has discussed and understands the implications of enrollment in a Part D plan on his or her employer or union coverage. Individuals will have 30 calendar days from the date they are contacted to respond. The PACE organization must ensure that plan benefits are available to the individual as of the effective date of the initial enrollment request. The organization may contact the individual in writing or by phone, or may discuss this in person and must document this contact and retain it with the record of the individual's enrollment request. If the individual indicates that s/he is fully aware of any consequence to his/her employer or union coverage brought about by enrolling in the Part D Plan, and confirms s/he still wants to enroll, the PACE organization must update the transaction with the appropriate "flag" (detailed instructions for this activity are included with CMS systems guidance) and re-submit it for enrollment. The effective date of enrollment will be based upon the individual's initial enrollment request. This effective date may be retroactive in the event that the confirmation step occurs after the effective date. Organizations may use the Code 62

enrollment transaction code to submit the enrollment transaction directly to CMS, as described in the Plan Communication Users Guide (PCUG).

- The Part D sponsor must use a number other than an enrollee's Social Security Number (SSN) or Healthcare Insurance Claim Number (HICN) on enrollee identification cards. (PACE Part D Solicitation);
- The Part D sponsor must provide the beneficiary's gross covered drug spend and true out-of-pocket (TrOOP) balance to the beneficiary as of the effective date of disenrollment. (PACE Part D Solicitation, PACE Plan Addendum –Implementation of Automated Troop Balance Transfer Process).

## Chapter 15 – PACE Organization Monitoring and Auditing

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### Table of Contents

<a href="#"><u>15.1 Introduction</u></a>	149
<a href="#"><u>15.2 General Monitoring and Auditing Requirements</u></a>	149
<a href="#"><u>15.2.1 PACE Organization Responsibilities</u></a>	149
<a href="#"><u>15.2.2 Technical Assistance</u></a>	149
<a href="#"><u>15.3 Audit</u></a>	150
<a href="#"><u>15.3.1 Pre-Audit Activities</u></a>	150
<a href="#"><u>15.3.2 Audit Process</u></a>	150
<a href="#"><u>15.3.2.1 Audit Team</u></a>	150
<a href="#"><u>15.3.2.2 Audit Guide</u></a>	150
<a href="#"><u>15.3.3 Audit Categories</u></a>	150
<a href="#"><u>15.3.3.1 Trial Period</u></a>	152
<a href="#"><u>15.3.3.1.1 Trial Period Review</u></a>	152
<a href="#"><u>15.3.3.1.2 Scope of Review</u></a>	152
<a href="#"><u>15.3.3.2 Biennial</u></a>	153
<a href="#"><u>15.3.3.3 Focused</u></a>	153
<a href="#"><u>15.4 Post Audit</u></a>	153
<a href="#"><u>15.4.1 CAR/CAP</u></a>	153
<a href="#"><u>15.4.2 Release from Corrective Action Plan</u></a>	154
<a href="#"><u>15.5 Disclosure of Results</u></a>	155
<a href="#"><u>15.6 State Administering Agency</u></a>	155

<a href="#"><u>15.6.1 Readiness Review</u></a>	155
<a href="#"><u>15.6.2 Monitoring During Trial Period</u></a>	155
<a href="#"><u>15.6.3 Annual Monitoring</u></a>	156
<a href="#"><u>15.6.4 Monitoring of Corrective Action Plans</u></a>	156
<a href="#"><u>15.7 Financial Recordkeeping and Reporting Requirements</u></a>	156
<a href="#"><u>15.7.1 Accurate Reports</u></a>	156
<a href="#"><u>15.7.2 Accrual Accounting</u></a>	156
<a href="#"><u>15.7.3 Accepted Reporting Practices</u></a>	157
<a href="#"><u>15.7.4 Trial Period Reporting Requirements</u></a>	157
<a href="#"><u>15.7.5 Annual Reporting Requirements</u></a>	157
<a href="#"><u>15.8 HPMS Quality Data Submission</u></a>	158

## **15.1 Introduction**

The PACE program agreement is a three-way agreement between the PACE organization, CMS and the State Administering Agency. Monitoring and auditing are the responsibility of CMS and the State Administering Agency.

[42 CFR § 460.30 and 460.112]

## **15.2 General Monitoring and Auditing Requirements**

As noted above, the State Administering Agency and CMS have primary responsibility to ensure that every PACE organization maintains compliance with State and Federal requirements. This function includes the monitoring and effectiveness evaluation of organizational structure, procedures, protocols, and policies of each PACE organization.

### **15.2.1 PACE Organization Responsibilities**

- The PACE organization shall collect data, maintain records and submit reports as required by CMS and the State Administering Agency. A PACE organization must submit to CMS and the State Administering Agency all reports that CMS and the State Administering Agency require to monitor the operation, cost, quality, and effectiveness of the program and establish payment rates. The PACE organization shall allow CMS and the State Administering Agency access to data and records including, but not limited to, participant health outcomes data, financial books and records, medical records, personnel records, any aspect of services furnished, reconciliation of participants' benefit liabilities and determination of Medicare and Medicaid amounts payable;
- The PACE organization agrees to require that all related entities, contractors or subcontractors agree that the State Administering Agency, the U.S. Department of Health and Human Services, CMS, or their designee(s) have the right to inspect, evaluate and audit any pertinent contracts, books, documents, papers, and records of any related entity contractor(s) or subcontractor(s) involving transactions related to the PACE Program Agreement.

[42 CFR §§ 460.70, 460.200(a), (b), and (c), and 460.204(d); 71 FR 71324 (Dec. 8, 2006)]

### **15.2.2 Technical Assistance**

CMS or the State Administering Agency may perform conference calls, webinars, or onsite visits to assist the PACE organization with operational or clinical issues. A PACE organization may request this assistance, or CMS or the State Administering Agency may provide technical assistance as a result of identified issues or opportunities for improvement.

## 15.3 Audit

### 15.3.1 Pre-Audit Activities

The pre-audit activities are very similar to those required for a Technical Advisory Visit. The PACE organization is required to provide operational and policy documents for review. Staff must be scheduled to be available for interview regarding administrative, clinical and Part D elements. In addition, documentation to validate actions performed concerning findings from the Technical Advisory Visit, prior audits, Level Two Reporting, monitoring outcomes and compliance actions may be requested during this phase or during the course of the audit. This aspect may include the results of previous routine and focused audits, including audits the State Administering Agency or other State and Federal entities may have conducted. A notice including the audit date, draft agenda, documentation request and other additional requirements will be sent to the PACE organization.

### 15.3.2 Audit Process

#### 15.3.2.1 Audit Team

The audit team consists of administrative and clinical staff from CMS and the State Administering Agency. The team reviews clinical, administrative and Part D elements as noted within the PACE Audit Guide. An external version of the guide is located on the CMS website at:

<http://www.cms.hhs.gov/PACE/Downloads/2008%20PACE%20Audit%20Guide.pdf>.

#### 15.3.2.2 Audit Guide

The PACE Audit Guide includes a listing of the elements by type – Administrative, Clinical and Part D. The guide also is an auditing tool that can be used by the PACE organization to perform a self assessment. The guide includes the regulatory requirements and a column to document whether the element was met or not met.

### 15.3.3 Audit Categories

Every PACE organization must have, as required by sections 1894(a)(9) and (e)(4) and 1934(a)(9) and (e)(4), an **annual audit during the PACE organization's trial period** - the first three contract years following the PACE organization program's effective date. **Routine or Biennial audits** are conducted at least every two years following a PACE organization's successful completion of the trial period audits. A **Focused audit** may be performed if CMS or the State Administering Agency determines that additional monitoring or auditing is required due to identified issues of non-compliance, operational deficiencies or significant audit findings. Focused audits may occur during the trial period or thereafter.

CMS does not share its method of evaluation or protocols with PACE organizations. The PACE organizations must comply with all PACE regulations, and preparations for audits should focus on a self-evaluation of the organization's compliance with PACE regulations. The PACE organizations must comply with local policies and procedures, and performance on monitoring requirements such as quarterly HPMS reporting elements. The elements covered include, but are not limited to, the following:

<b>Element</b>	<b>Title</b>
<b>Section 1 – Clinical PACE Elements</b>	
PRS 02	Personnel Training
PRS 04	Oversight of Direct Patient Care
ENV 01	Physical Environment
ENV 02	Infection Control
TRS 01	Transportation Services
DTY 01	Dietary Services
SDY 01	Service Delivery
SDY 02	Emergency Care
SDY 03	Interdisciplinary Team
SDY 04	Participant Assessment
SDY 05	Plan of Care
QAP 04	Internal Quality Assessment and Performance Improvement Activities
<b>Section 2 A – Administrative PACE Elements</b>	
CTS 01	Contracted Services
FIN 01	Fiscal Soundness
PRT 04	Explanation of rights
PRT 06	Grievance Process
PRT 07	PACE Organization's Appeals Process
PRT 08	Additional Appeal Rights Under Medicare or Medicaid
MKT 03	Enrollment Process
MKT 08	Voluntary Disenrollment
MKT 09	Involuntary Disenrollment
<b>Section 2B – Operational Part D Elements</b>	
ER 13	Confirmation of Enrollment for Members of Employer Group/Union
PR 02	Use of SSN/HICN
EP01	Electronic Prescribing
CB 01	Collecting/Updating Enrollees' Other health Insurance Information
CB03	TrOOP Status at Disenrollment
CP06	Internal Monitoring and Auditing Procedures
CP07	Response to Detected Offenses and Corrective Action Plan
CP08	Comprehensive Fraud and Abuse Plan
CL01	Online Claims Processing System

CL02	Data Elements Needed to Link Medicare Parts A, B and D Data
CL03	Processing Systems
CL04	Disputed Claims
CL06	Certification of Claims Data
PA 01	Certification of Monthly Enrollment and Payment Data Relating to CMS Payment
PA02	Submission of Prescription Drug Event Data
PA03	Overpayment and Underpayment Requirements

### **15.3.3.1 Trial Period**

Trial period means the first three contract years in which a PACE organization operates under a PACE Program Agreement, including any contract year during which the entity operated under a PACE demonstration waiver program. The first contract year can extend up to 23 months for purposes of the audit period, that is, to December 31<sup>st</sup> of the year following the effective date of the contract, in order to allow the PACE organization to enroll participants and to become fully operational before the first trial period audit is conducted, and the first trial period audit can be conducted at any point during this 23-month period.

[42 CFR §§ 460.6 and 460.190(a)]

#### **15.3.3.1.1 Trial Period Review**

During the trial period, CMS, in cooperation with the State Administering Agency, conducts comprehensive annual reviews of the operations of a PACE organization to ensure compliance.

[42 CFR § 460.190]

#### **15.3.3.1.2 Scope of Review**

As noted above, the review includes the utilization of the PACE Audit Guide. In addition, the review may include performance of the following:

- An onsite visit to the PACE organization, which may include, but is not limited to, the following:
  - o Review of participants' charts;
  - o Interviews with staff;
  - o Interviews with participants and caregivers; and,

- o Interviews with contractors;
- Observation of program operations, including marketing, participant services, enrollment and disenrollment procedures, grievances, and appeals;
- A comprehensive assessment of an organization's fiscal soundness;
- A comprehensive assessment of the organization's capacity to furnish all PACE services to all participants; and

Any other elements that CMS or the State Administering Agency find necessary.

#### **15.3.3.2 Biennial**

At the conclusion of the trial period, CMS, in cooperation with the State Administering Agency, continues to conduct reviews of a PACE organization, as appropriate. These reviews take into account the performance level of the PACE organization with respect to the quality of care provided and compliance of the organization in meeting the PACE program requirements. Such reviews include an on-site visit at least every two years.

[42 CFR § 460.192]

#### **15.3.3.3 Focused**

After the trial period, CMS or the State Administering Agency may determine that a PACE organization has some areas of their program that need further monitoring. In these situations, CMS or the SAA may perform Focused Audits on these or other areas. These audits may be announced or unannounced onsite or offsite audits.

[42 CFR § 460.192]

### **15.4 Post Audit**

CMS, the State Administering Agency or their designees will deliver an audit report containing findings, deficiencies, corrective action required, recommendations, notes and conclusions to the PACE organization concerning the audit. A letter detailing instructions, as noted below, is mailed to the primary contact for the PACE organization.

[42 CFR § 460.196(a)]

#### **15.4.1 CAR/CAP**

A PACE organization must take action to correct deficiencies identified during reviews. Corrective Action Required (CAR) and Corrective Action Plan (CAP) are formal processes

where CMS informs PACE organizations that they are out of compliance with CMS requirements. Corrective Action Required (CAR)/Corrective Action Plan (CAP) may result from a PACE audit or result from other ad-hoc compliance events unrelated to an audit. For example, CMS issues a compliance warning letter to a PACE organization and the PACE organization fails to satisfactorily resolve the matter cited in the warning letter.

More specifically, Corrective Action Required (CAR) letters are issued when CMS identifies an area of concern that requires a formal plan for a demonstrated cure. A Corrective Action Required (CAR) should be considered when a PACE organization has not provided a satisfactory response to a single warning letter on a specific subject (an egregious single event) or the issue is of a highly serious nature.

A Corrective Action Required (CAR) letter may also be issued by CMS directly to the PACE organization when CMS has identified an ad hoc compliance event. Once a PACE organization receives a CAR letter, they would respond to CMS with either a dispute of findings or a Corrective Action Plan (CAP).

The PACE organization must provide a plan containing actions, activities, policies and procedures that will be implemented to correct the deficiencies and to be in compliance. The PACE organization must respond promptly to the deficiencies following receipt of formal notice from CMS via an HPMS email. The Corrective Action Plan is promptly reviewed by CMS following receipt of the PACE organization's submission of the Corrective Action Plan. If the Corrective Action Plan is unacceptable, a PACE organization will be provided an opportunity to promptly resubmit a revised Corrective Action Plan. CMS will review the revised Corrective Action Plan and provide a prompt response.

Corrective Action Plans are public documents which are posted on the CMS website at <http://www.cms.hhs.gov/MCRAdvPartDENrolData/>.

[42 CFR § 460.196(b)]

#### **15.4.2 Release from Corrective Action Plan**

Once CMS accepts the Corrective Action Plan, the PACE organization must implement the CAP. The amount of time allowed to implement a Corrective Action Plan depends on the number of deficiencies and the complexity of the deficiencies. CMS or the State Administering Agency monitors the implementation and effectiveness of corrective actions to determine if adequate progress is being made on the CAP before giving consideration to releasing the PACE organization from its Corrective Action Plan.

The Corrective Action Plan process ends when the PACE organization has fully implemented the CAP and CMS formally releases the PACE organization from the Corrective Action Plan. The Corrective Action Plan release process occurs via an HPMS-generated notice.

CMS or the State Administering Agency may take enforcement action if the PACE organization fails to submit an acceptable Corrective Action Plan to CMS or if the PACE organization fails to satisfactorily implement an accepted Corrective Action Plan. Failure to develop and implement a Corrective Action Plan within the timeframes specified by CMS may result in sanctions or termination of a PACE organization's contract by CMS or the State Administering Agency.

[42 CFR § 460.194(b) and (c)]

## **15.5 Disclosure of Results**

CMS and the State Administering Agency promptly report the results of reviews to the PACE organization, along with any recommendations for changes to the organization's program. The results are made available to the public upon request and as posted on the CMS website. In addition, CMS and the State Administering Agency require that the PACE organization post a notice of the availability of the results of the most recent review and any Corrective Action Plans or responses related to the most recent review. The PACE organization must also make the results available for examination in a place readily accessible to participants.

[42 CFR § 460.196]

## **15.6 State Administering Agency**

The State Administering Agency assures that its responsibilities under Sections 1894 and 1934 of the Social Security Act will be met. All relevant provisions are included in the contract with the PACE entities, either as a contractor or State Administering Agency responsibility. Both scheduled and unscheduled on-site reviews will be conducted by State Administering Agency staff.

[42 CFR §§ 460.30, 460.32, 460.190, and 460.192]

### **15.6.1 Readiness Review**

The State Administering Agency will perform a Readiness Review of the applicant entity that assures the entity has fully developed its policies and procedures, obtained commitments from key staff, developed its solvency plan and has a facility that meets State and Federal requirements at the time of the application.

[42 CFR § 460.12(b)(1); 71 FR 71252 (Dec. 8, 2006)]

### **15.6.2 Monitoring During Trial Period**

During the trial period, the State Administering Agency, in cooperation with CMS, will conduct comprehensive reviews of a PACE organization to ensure compliance with State and Federal requirements. At the conclusion of the trial period, the State Administering Agency, in cooperation with CMS, will continue to conduct reviews of a PACE organization, as appropriate, taking into account the quality of care furnished and the organization's compliance with State and Federal requirements.

[42 CFR §§ 460.190(c) and 460.192(a)]

### **15.6.3 Annual Monitoring**

The State Administering Agency assures that at least annually it will reevaluate whether a participant meets the level of care required under the State Medicaid plan for coverage of nursing facility services. The State Administering Agency understands that this determination may be waived if there is no reasonable expectation of improvement or significant change in the participant's conditions because of the severity of a chronic condition or the degree of impairment of functional capacity. The State Administering Agency assures that it will make reviews conducted in accordance with 42 CFR § 460.190 and 42 CFR §460.192 available to the public upon request.

[42 CFR §§ 460.160(b)(a) and 460.196(b)]

### **15.6.4 Monitoring of Corrective Action Plans**

CMS works in partnership with the State Administering Agency to monitor the effectiveness of corrective actions required to be taken by the PACE organization.

[42 CFR § 460.194(b)]

## **15.7 Financial Recordkeeping and Reporting Requirements**

### **15.7.1 Accurate Reports**

A PACE organization must provide CMS and the State Administering Agency with accurate financial reports that are:

- Prepared using an accrual basis of accounting; and
- Verifiable by qualified auditors.

[42 CFR § 460.204(a)]

### **15.7.2 Accrual Accounting**

A PACE organization must maintain an accrual accounting recordkeeping system that does the following:

- Accurately documents all financial transactions;
- Provides an audit trail to source documents;
- Generates financial statements.

[42 CFR § 460.204(b)]

### **15.7.3 Accepted Reporting Practices**

Except as specified under Medicare principles of reimbursement, a PACE organization must follow standardized definitions, accounting, statistical, and reporting practices that are widely accepted in the health care industry.

[42 CFR § 460.204(c)]

### **15.7.4 Trial Period Reporting Requirements**

Throughout a trial period, the PACE organization is required to submit a quarterly financial statement to CMS within forty-five days after the last day of each quarter of the organization's fiscal year. These statements are not required to be certified by an independent certified public accountant. After the trial period, CMS and/or the State Administering Agency may require a PACE organization to submit monthly and/or quarterly financial statements or both if there are concerns about the fiscal soundness of the organization.

[42 CFR § 460.208(c)]

### **15.7.5 Annual Reporting Requirements**

CMS requires the PACE organization to submit an annual financial statement with appropriate footnotes no later than 180 days after the end of the organization's fiscal year. The financial statement must be certified by an independent certified public accountant and at a minimum include the following items:

- Certification statement;
- Balance sheet;
- Statement of revenues and expenses; and
- Source and use of funds statement.

[42 CFR § 460.208(a) and (b)]

## **15.8 HPMS Quality Data Submission**

PACE organizations are required to maintain a health information system that collects, analyzes, integrates, and reports data necessary to measure their performance and to develop their QAPI.

HPMS is a CMS internal health information system that collects, analyzes, integrates, and reports data to measure the organization's performance [42 CFR § 460.202(a)] and to develop and implement procedures to furnish data pertaining to the provision of care to external oversight entities in the manner and at the time intervals specified by CMS and the State Administering Agency [42 CFR § 460.202(b), 42 CFR § 460.140]. A PACE organization must submit to CMS and the State Administering Agency all reports required to monitor the operation, costs, quality, and effectiveness of the PACE program and establish payment rates.

In developing procedures for external reporting, the PACE organization must include the submission of CMS monitoring data which is specified as "participant data" in Appendix L of the PACE Program Agreement. CMS requires the data to be reported quarterly/seasonally through the HPMS system.

The nine data elements are listed below:

- Routine immunizations (i.e., influenza and pneumococcal pneumonia immunizations);
- Grievances and appeals;
- Enrollments;
- Disenrollments;
- Prospective enrollees;
- Readmissions to acute care hospitals;
- Emergent (unscheduled) care (emergency department in hospital or outpatient clinic);
- Unusual incidents for participants and the PACE site, including staff if a participant was involved (e.g., falls, van accidents, suicide, attempted suicide, medication errors, participant injuries, etc.); and

- Deaths.

PACE programs are required to submit Data Elements for Monitoring on a quarterly basis via the HPMS. HPMS information may be used by CMS and State Administering Agencies in the time period before or after signing the program agreement which contains these reporting requirements, PACE organizations are provided with instructions on the HPMS: The HPMS Connectivity Guide, HPMS User's Guide and HPMS Connectivity for States. These materials can also be found on the CMS Web site at [http://www.cms.hhs.gov/PACE/09\\_AdditionalResources.asp](http://www.cms.hhs.gov/PACE/09_AdditionalResources.asp).

[42 C.F.R §§ 460.134, 460.140 460.200, 460.204, 71 FR 71307 (Dec. 8, 2006)]

## Chapter 16 - PACE Sanctions, Enforcement Actions and Termination

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### Table of Contents

<a href="#"><u>16.1 Introduction</u></a>	161
<a href="#"><u>16.2 Enforcement</u></a>	161
<a href="#"><u>16.3 Violations for which CMS May Impose Sanctions</u></a>	161
<a href="#"><u>16.4 Suspension of Enrollment or Payment by CMS</u></a>	162
<a href="#"><u>16.5 Civil Money Penalties (CMP's)</u></a>	163
<a href="#"><u>16.6 Additional Actions by CMS or the State</u></a>	163
<a href="#"><u>16.7 Termination of the PACE Program Agreement</u></a>	164
<a href="#"><u>16.7.1 Transitional Care</u></a>	164
<a href="#"><u>16.7.2 Termination Procedures</u></a>	165

## **16.1 Introduction**

PACE is a partnership between CMS, the State, and the PACE organization. CMS and the State work together to ensure the benefits and services provided are of high quality and meet the requirements set forth in the statute and regulations and by the State in which the PACE organization resides. When compliance actions fail to achieve the desired result or an instance of non-compliance is especially egregious, CMS may take enforcement action. CMS recognizes that in addition to the sanctions, enforcement actions and termination set forth below, each State will have their own actions that may be implemented when a PACE organization is out of compliance.

## **16.2 Enforcement**

Enforcement activity begins when: (1) deficiencies are serious enough to escalate directly to the enforcement activity stage and/or; (2) core compliance deficiencies remain unresolved during the compliance activity stage after providing the PACE organization with the appropriate notice and opportunity to correct the deficiencies.

Enforcement actions (also known as “intermediate sanctions”) include the following two categories of actions: (1) enrollment and/or payment suspensions and; (2) civil money penalties (CMPs). Enrollment and payment suspensions are imposed for serious contractual deficiencies defined by statute and are designed to ensure the deficiencies which formed the bases for the sanction are corrected and not likely to recur. CMPs are also intended to be imposed for serious contractual deficiencies defined by statute and are designed to be punitive in nature. Depending on the particular deficiency and statutory basis for taking the action, CMS may impose both suspensions of enrollment and payment and a CMP.

[42 CFR §§ 460.40 et seq]

## **16.3 Violations for which CMS May Impose Sanctions**

There are specific violations for which CMS may impose sanctions on the PACE organization and they are as follows:

- The PACE organization fails substantially in furnishing the medically necessary items and services to the participant that are covered by PACE if the failure has adversely affected (or has a substantial likelihood of adversely affecting) the participant;
- The PACE organization involuntarily disenrolls a participant in violation of 42 CFR § 460.164;
- The PACE organization discriminates on the basis of an individual’s health status or need for health care services in the enrollment or disenrollment process, among

Medicare beneficiaries or Medicaid recipients, or both, who are eligible to enroll in a PACE program;

- The PACE organization engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment, except as permitted by 42 CFR § 460.150 by Medicare beneficiaries or Medicaid recipients whose medical condition or history indicates a need for substantial future medical services;
- The PACE organization imposes premium charges on a participant enrolled under Medicare or Medicaid that is more than the allowable amount;
- The PACE organization misrepresents or falsifies information that is furnished to CMS or the State or, to an individual or any other entity under part 460;
- The PACE organization prohibits or restricts a covered healthcare professional, who is acting within their lawful scope of practice, from advising a participant (their patient) about the patient's health status, medical care, or treatment for the participant's condition or disease, regardless of whether the PACE program provides the benefits for that care or treatment;
- The PACE organization operates a physician incentive plan that does not meet the requirements of Section 1876(i)(8) of the Act;
- The PACE organization employs or contracts with any individual who is excluded from participation in Medicare or Medicaid under Section 1128 or 1128A of the Act (or with any entity that employs or contracts with such an individual) for the provision of health care, utilization review, medical social work, or administrative services.

[42 CFR § 460.40]

#### **16.4 Suspension of Enrollment or Payment by CMS [**

CMS may suspend enrollment of Medicare beneficiaries due to the above mentioned violation after the date CMS notifies the PACE organization of the violation. For individuals enrolled after the date CMS notifies the PACE organization of the violation, CMS may suspend Medicare payment to the PACE organization and deny payment to the State of Federal Financial Participation for medical assistance for services furnished under the PACE program agreement. The State Administering Agency determines if suspension of enrollment should occur with Medicaid recipients. A suspension or denial of payment remains in effect until CMS is satisfied that the PACE organization has corrected the cause of the violation and the violation is not likely to recur.

[42 CFR § 460.42; 71 FR 71259 (Dec. 8, 2006)]

## **16.5 Civil Money Penalties (CMP's)**

There are certain violations for which CMS will impose a civil money penalty. The penalty is amounts up to the following maximum amounts, depending on the type of violation.

Civil money penalty violations include:

- For each violation regarding enrollment or disenrollment specified in 42 CFR § 460.40(c) or (d), \$100,000 plus \$15,000 for each individual not enrolled as a result of the PACE organization's discrimination in enrollment or disenrollment or practice that would deny or discourage enrollment;
- For each violation regarding excessive premiums specified in 42 CFR § 460.40(e), \$25,000 plus double the excess amount above the permitted premium charged a participant by the PACE organization (the excess amount charged is deducted from the penalty and returned to the participant);
- For each misrepresentation or falsification of information as specified in 42 CFR § 460.40(f)(1), \$100,000;
- For any other violation specified in 42 CFR § 460.40, \$25,000;
  - The provisions of section 1128A of the Act (other than subsections (a) and (b)) apply to a civil money penalty under this section in the same manner as they apply to a civil money penalty or proceeding under section 1128A(a).

[42 CFR § 460.46]

## **16.6 Additional Actions by CMS or the State**

After CMS consults with the State Administering Agency, if CMS determines the PACE organization is not in substantial compliance with the PACE requirements, CMS or the State Administering Agency can take one or more of the following actions:

- The continuation of the PACE Program Agreement is contingent on the PACE organization's timely execution of a corrective action plan;
- The PACE organization must correct the deficiency or CMS and/or the State Administering Agency can withhold some or all payments under the PACE agreement;
- Termination of the PACE Program Agreement.

[42 CFR § 460.48]

## **16.7 Termination of the PACE Program Agreement**

CMS or State Administering Agency may terminate a PACE Program Agreement at any time for cause and a PACE organization may terminate an agreement after appropriate notice to CMS, State Administering Agency and its participants. CMS or the State Administering Agency may terminate a PACE Program Agreement with the PACE organization for cause including, but not limited to, the following:

- There are significant deficiencies in the quality of care furnished to participants or the PACE organization has failed to comply substantially with conditions for a PACE program or PACE organization under the Part 460 regulations or with the terms of its PACE Program Agreement; and, within 30 days of the date of receipt of the written notice regarding the deficiencies, the PACE organization failed to develop and successfully initiate a plan to correct the deficiencies or failed to continue implementation of such a plan, or CMS and the State Administering Agency determined that the deficiencies cannot be corrected; or
- CMS or the State Administering Agency determines that the PACE organization cannot ensure the health and safety of its participants. The determination may result from the identification of deficiencies that CMS or the State Administering Agency determines cannot be corrected.

If the PACE organization initiates the termination, it is required to give CMS and the State Administering Agency 90 days notice and participants 60 days notice before termination in order to provide sufficient time to transition participants to alternative care. If a participant is eligible for Medicaid, the State should provide assistance in arranging for the alternative care. Neither the State nor CMS considers termination lightly. The primary concern is protecting the health and safety of the participant and all possible ramifications of terminating a program agreement, including the likelihood of participants becoming institutionalized, will be considered before taking such severe action.

[42 CFR § 460.50; 71 FR 71261 (Dec. 8, 2006)]

### **16.7.1 Transitional Care**

The PACE organization must develop a detailed written plan for phase-down in the event of termination. Such plan must describe how the organization plans to take the following actions:

- The plan must include a process for informing participants, the community, CMS and the State Administering Agency in writing about the termination and transition phases;

- The steps that the PACE organization will take to assist participants to obtain reinstatement of conventional Medicare and Medicaid benefits;
- Transitioning the participants' care to other providers;
- Termination of marketing and enrollment activities.

An entity whose PACE Program Agreement is in the process of being terminated must implement its phase-down plan discussed above and provide assistance to each participant in obtaining necessary transitional care through appropriate referrals and ensuring that the participants' medical records available to new providers.

Additional information can be found at <http://www.cms.hhs.gov/PACE/>.

[42 CFR § 460.52]

### **16.7.2 Termination Procedures**

If CMS terminates an agreement with a PACE organization, it furnishes the PACE organization with the following: (1) a reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of CMS's determination that cause exists for termination; and (2) reasonable notice and opportunity for a hearing, including the right to appeal an initial determination, before terminating the agreement.

CMS may terminate an agreement without invoking any of the above mentioned procedures if CMS determines that a delay in termination, resulting from compliance with these procedures before termination, would pose an imminent and serious risk to the health of participants enrolled with the organization.

## **Chapter 17 - PACE Application and Waiver Processes, and Program Agreement Requirements**

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### Table of Contents

<a href="#"><u>17.1 Overview of CMS and State Administering Agency Roles and Responsibilities</u></a>	167
<a href="#"><u>17.2 CMS</u></a>	167
<a href="#"><u>17.2.1 Provider Application</u></a>	167
<a href="#"><u>17.2.1.1 Limit on the Number of PACE Program Agreements</u></a>	169
<a href="#"><u>17.2.2 Expansion Application</u></a>	169
<a href="#"><u>17.2.2.1 Scenario 1</u></a>	170
<a href="#"><u>17.2.2.2 Scenario 2</u></a>	170
<a href="#"><u>17.2.2.3 Scenario 3</u></a>	170
<a href="#"><u>17.2.3 BIPA 903 Waivers</u></a>	171
<a href="#"><u>17.3 State</u></a>	173
<a href="#"><u>17.3.1 PACE State Plan Amendment</u></a>	173
<a href="#"><u>17.3.2 State Readiness Review</u></a>	173
<a href="#"><u>17.3.3 State Contract</u></a>	174
<a href="#"><u>17.4 PACE Program Agreement</u></a>	174
<a href="#"><u>17.5 Effect of Change of Ownership</u></a>	176

## **17.1 Overview of CMS and State Administering Agency Roles and Responsibilities**

The regulations issued by CMS for PACE, issued November 24, 1999, established requirements for PACE under the Medicare and Medicaid programs. The second regulation published on October 1, 2002, incorporated revisions to the original regulation, implementing Section 903 of MIPPA (Pub. L. 106–554) by establishing a process through which PACE organizations may request waiver of certain regulatory requirements. In addition, it provided for greater flexibility in adapting the PACE service delivery model to the needs of the particular organization and removed the requirement that PACE organizations directly employ the interdisciplinary team, the program director, and medical director and allowed for these positions to be contracted. The final rule incorporating response to comments and updates to the regulation was published December 8, 2006.

Section 1905(a)(26) of the Act, as added by Section 4802(a)(1) of the BBA, provided authority for States to elect PACE as an optional Medicaid benefit. States notify CMS that they have elected PACE as an option via a State Plan Amendment that is to be submitted to CMS by the State Medicaid Agency. Each State is required to have a State Administering Agency that is responsible for administering PACE Program Agreements in their State. The State Medicaid Agency may or may not be the State Administering Agency. The State Administering Agency closely cooperates with CMS in establishing procedures for entering into, extending, and terminating PACE Program Agreements. The State Administering Agency also cooperates with CMS in conducting oversight reviews of PACE programs and has the authority to terminate a PACE Program Agreement for cause.

The State Administering Agency is responsible for conducting a readiness review during the application approval process to ensure that the PACE center meets the regulatory requirements for environment and staffing.

It is the responsibility of the PACE organization and the State Administering Agency to validate the information contained in each application. The Director of the State Administering Agency confirms review and approval of the application by submitting a signed certification with the application.

## **17.2 CMS**

### **17.2.1 Provider Application**

Information requested in the provider application is based on sections 1894 and 1934 of the Social Security Act, and the regulations at 42 CFR § 460.2 thru 460.210.

An individual authorized to act for the entity must submit to CMS a complete application that describes how the entity meets all requirements of part 460. It is the responsibility of the PACE organization and the State Administering Agency to validate the information contained in each application. An entity's application must be accompanied by an assurance

from the State Administering Agency of the State in which the program is located indicating that the State considers the entity to be qualified to be a PACE organization; and is willing to enter into a PACE program agreement with the entity.

A completed application includes:

- Cover Sheet with the appropriate signatures;
- Table of Contents for the Narrative part;
- Table of Contents for Documents part;
- Narrative part, with each question copied and brief and precise answers, divided into chapters;
- Documents part, arranged by chapters; this part should follow the Narrative. Materials such as marketing brochures and booklets should be inserted in envelopes in the appropriate places in the application. The envelope should be numbered as a single page.

The PACE Provider Application and related resources are located on the CMS webpage at: [http://www.cms.hhs.gov/PACE/06\\_ProviderApplicationandRelatedResources.asp#TopOfPage](http://www.cms.hhs.gov/PACE/06_ProviderApplicationandRelatedResources.asp#TopOfPage) . This Provider Application has been updated to reflect the provisions of the December 2006 final PACE regulation. This file is in a zipped rich text format so States can download a writeable version for submission. It also contains appendices (including the Provider Arrangements File, Insurance Coverage File, and Payment Information Form) that must be submitted to CMS as part of the PACE Provider Application.

CMS evaluates an application for approval as a PACE organization on the basis of the information contained in the application, information obtained through onsite visits conducted by CMS or the State Administering Agency, and information obtained by the State Administering Agency.

An entity must state in its application the service area it proposes for its program. CMS, in consultation with the State Administering Agency, may exclude from designation an area that is already covered under another PACE program agreement to avoid unnecessary duplication of services and avoid impairing the financial and service viability of an existing program.

A PACE application can be submitted at any time during the year. As stated in 42 CFR 460.20, within 90 days after an organization submits a complete application to CMS, CMS can (1) approve the application; (2) deny the application and notify the entity in writing of the basis for denial and the process for requesting reconsideration of the denial; or (3) request additional information needed to make a final determination. Upon receipt of all of the

responses to the request for additional information and the completed State Readiness Review, CMS has an additional 90 days to either approve the application or disapprove the application and notify the entity in writing of the basis for the denial and the process for requesting reconsideration of the denial. An application is deemed approved if CMS fails to act on the application within 90 days after the date the application is submitted by the organization or the date CMS receives all requested additional information. For purposes of the 90-day time limit, the date that an application is submitted to CMS is the date on which the application is delivered to the address designated by CMS.

[42 CFR §§ 460.12(a)(1) and (b), 460.18, 460.20, 460.22 and 460.72]

### **17.2.1.1 Limit on the Number of PACE Program Agreements**

There is a limit on the number of PACE program agreements that may be in effect on August 5 of each year, the anniversary of the PACE statute. The number of PACE organizations with which agreements are in effect, are not permitted to exceed:

- Forty as of August 5, 1997, the date of enactment of the PACE statute, or
- As of each succeeding anniversary of that date, the numerical limitation for the preceding year plus 20.

Based on the statutory language, we may enter into up to 80 PACE program agreements as of August 5, 1999, and the limit on the number of PACE program agreements increases by 20 each year thereafter.

[42 CFR §§ 460.24]

### **17.2.2 Expansion Application**

The most current version of the **PACE Expansion Application** is available at [http://www.cms.hhs.gov/PACE/07\\_Expansions.asp#TopOfPage](http://www.cms.hhs.gov/PACE/07_Expansions.asp#TopOfPage).

The application is required for PACE organizations wishing to expand their service area or add a new PACE center. In order to ensure quality of care for PACE participants, CMS will only approve an expansion application after an organization has completed the first trial period audit and achieved an acceptable corrective action plan for the initial PACE center and service area.

There are three scenarios under which a PACE provider may expand operations. Each scenario described below contains a list of steps that must be followed for expansion approval.

#### **17.2.2.1 Scenario 1: A PACE Organization requests to expand its geographic service area without building additional sites**

- PACE organization must obtain approval for expansion from State Medicaid Agency (SMA) and State Administering Agency;
- PACE organization and State Administering Agency collaborate on the provider application in its entirety. To the extent the expanded service area reflects the same processes as the already approved service area of the provider, the application can note this without resubmitting approved material;
- For an expansion application for a geographic service area expansion only, CMS has 45 days to request additional information or approve the application. Upon the receipt of responses to the request for additional information, CMS has an additional 45 days to either approve or disapprove the application;
- If approved, the Program Agreement's Appendix C is amended to reflect the new service area.

#### **17.2.2.2 Scenario 2: A PACE Organization requests to open another physical site in the existing geographic service area**

- PACE organization must obtain approval for expansion from State Medicaid Agency and State Administering Agency;
- PACE organization and State Administering Agency collaborate on the provider application in its entirety. To the extent the new site adopts the same processes as the already approved sites of the provider, the application can note this without resubmitting approved material;
- The State Administering Agency conducts a State Readiness Review of the new site while the clock is stopped;
- For an expansion application for only a new center within an existing geographical area, CMS has 45 days to request additional information or approve the application. Upon completion of the State Readiness Review and receipt of responses to the Request for Additional Information, CMS has an additional 45 days to either approve or disapprove the application;
- If approved, the Program Agreement's Appendix C is amended to reflect the new site.

#### **17.2.2.3 Scenario 3: A PACE Organization requests to expand its geographic service area and open another physical site in the expanded area**

- PACE organization must obtain approval for expansion from State Medicaid Agency and State Administering Agency;
- PACE organization and State Administering Agency collaborate on the provider application in its entirety. To the extent the new site adopts the same processes as the already approved sites of the provider, the application can note this without resubmitting approved material;
- The State Administering Agency conducts a readiness review of the new site while the clock is stopped;
- For an application to expand both service area and add a new center, CMS has 90 days to either request additional information or approve the application. Upon completion of the State Readiness Review and receipt of the responses to the request for additional information, CMS has an additional 90 days to either approve or disapprove the application;
- If approved, the Program Agreement's Appendix C is amended to reflect the new geographic area and new site.

[http://www.cms.hhs.gov/PACE/07\\_Expansions.asp#TopOfPage](http://www.cms.hhs.gov/PACE/07_Expansions.asp#TopOfPage)

### **17.2.3 BIPA 903 Waivers**

The purpose of the waivers is to provide for reasonable flexibility in adapting the PACE model to the needs of particular organizations (such as those in rural areas). Sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act provide for reasonable flexibility in adapting the PACE service delivery model to the needs of particular organizations and permit the Secretary in close consultation with State Administering Agencies to modify or waive provisions of the PACE protocol so long as any such modification or waiver is not inconsistent with and would not impair the essential elements, objections, and requirements of these sections. These sections state that the following provisions may not be modified or waived:

- The focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility;
- The delivery of comprehensive, integrated acute and long-term care services;
- The IDT approach to care management and service delivery;
- Capitated, integrated financing that allows the provider to pool payments received from public and private programs and individuals; and

- The assumption by the provider of full financial risk.

Section 903 of BIPA addresses flexibility in exercising the waiver authority provided under sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act. Section 903 of the BIPA states that the Secretary may exercise authority to modify or waive such provisions in a manner that responds promptly to the need of PACE programs relating to areas of employment and the use of community-based primary care physicians.

The CMS advises PACE organizations to engage in dialogue with their State Administering Agency regarding considerations for waiver requests prior to preparing formal requests. This will help to ensure mutual understanding and agreement among parties involved, preventing unnecessary work on the part of the PACE organization.

The following CMS link provides instructions for both PACE organizations and State administering agencies in submitting BIPA 903 waivers to CMS:

[http://www.cms.hhs.gov/PACE/08\\_BIPA903WaiverRequests.asp#TopOfPage](http://www.cms.hhs.gov/PACE/08_BIPA903WaiverRequests.asp#TopOfPage).

Instructions to PACE organizations for preparing and submitting waiver requests to State administering agencies under the authority of Section 903 of the BIPA are as follows:

- Any PACE organization that identifies the need for a BIPA 903 waiver should include the following information in their waiver submission package:
  - o Identification that the submitted document is a waiver request;
  - o Identification of the regulatory section the PACE organization is requesting to have waived;
  - o Rationale behind the waiver request;
  - o If applicable, process that will be followed to ensure participant care is not compromised; and
  - o Identification as to whether the issue was previously submitted as a BIPA 902 grandfathering request or if it is a new request under section 903 of BIPA;
- Waiver requests may be submitted to the State under either of the following situations:
  - o Waiver request as a document separate from an application but accompanying an application; or
  - o Waiver request independent of an application.

Waiver requests submitted in conjunction with provider applications must be marked as separate documents by placing them in an independent envelope labeled "waiver request." Waiver requests submitted independent of an application, as stand-alone documents must also be clearly labeled "waiver request".

Waiver requests must be submitted to the State Administering Agency. The request will be reviewed by the State and then forwarded to CMS along with any concerns or conditions. CMS evaluates a waiver request from a PACE organization or PACE applicant on the basis of the following information: (1) the adequacy of the description and rationale for the waiver provided by the PACE organization or PACE applicant, including any additional information requested by CMS; and (2) information obtained by CMS and the State Administering Agency in on-site reviews and monitoring of the PACE organization. Within 90 days after receipt of a waiver request, CMS either approves the request or denies the request and notifies the PACE organization or PACE applicant in writing of the basis of the denial. For purposes of the 90-day time limit, the date that a waiver request is received by CMS from the State Administering Agency is the date on which the request is delivered to the address designated by CMS. A waiver request is deemed approved if CMS fails to act on the request within 90 days after the date the waiver request is received by CMS. CMS may withdraw approval of a waiver for good cause.

[42 CFR §§ 460.10, 460.26, and 460.28]

[http://www.cms.hhs.gov/PACE/08\\_BIPA903WaiverRequests.asp#TopOfPage](http://www.cms.hhs.gov/PACE/08_BIPA903WaiverRequests.asp#TopOfPage)

## **17.3 State**

### **17.3.1 PACE State Plan Amendment**

In order to elect PACE as a State plan option, a State Medicaid Agency must submit a State Plan Amendment. The preprint for a State to elect PACE is found at [www.cms.hhs.gov/PACE](http://www.cms.hhs.gov/PACE). The State Plan Amendment must be approved before CMS can enter into a PACE Program Agreement.

[42 CFR § 460.30(c)]

### **17.3.2 State Readiness Review**

States are responsible for conducting a State Readiness Review at the applicant's site.

The purpose of this review is to determine the organization's readiness to administer the PACE program and enroll participants. The SRR includes a minimum set of criteria established by CMS in conjunction with the States. States are free to add any additional criteria to the State Readiness Review they deem necessary to help them determine if the applicant (1) meets the requirements stipulated in the PACE regulation; (2) has developed

policies and procedures consistent with the PACE regulations; and (3) has established the contracts necessary to provide all inclusive, quality care to its participants. Upon completion of the SRR, the State will submit a report of their findings to CMS. More information on the SRR can be found on the CMS website at:

[www.cms.hhs.gov/PACE/04\\_InformationforStateAgencies.asp#TopOfPage](http://www.cms.hhs.gov/PACE/04_InformationforStateAgencies.asp#TopOfPage).

During the initial and expansion application processes, the second clock may not begin until all of the elements of the State Readiness Review tool are met to the satisfaction of the State and submitted to CMS.

### **17.3.3 State Contract**

The PACE Program Agreement is a three-way contract between the PACE organization, the State Administering Agency and CMS, and contains the PACE requirements from the Federal statute and regulations. If the State Administering Agency has requirements beyond those in the three-way PACE Program Agreement, those requirements should be addressed in a separate contract between the State and the PACE organization. The PACE three-way program agreement can be an attachment to the State- PACE organization contract. The State contract with the PACE organization cannot be attached or included as part of the three-way agreement. Each PACE organization must agree to meet all applicable requirements under Federal, State, and local laws and regulations.

States may implement additional or more stringent requirements if they are consistent with Sections 1894 and 1934 of the Act and with Federal laws and regulations. However, if there is a conflict between the State and Federal requirements, the Federal requirements would take precedence.

[42 CFR §§ 460.30(a) and 460.32(a)(2); 71 FR 71258 (Dec. 8, 2006)]

### **17.4 PACE Program Agreement**

The PACE Program Agreement is the contract executed between CMS, State Administering Agency and the PACE organization upon approval of a permanent PACE provider application.

This three-party contract governs provider operations and is signed by the aforementioned parties. A PACE program agreement must include the following:

- A designation of the service area of the organization's program. The area may be identified by county, zip code, street boundaries, census tract, block, or tribal jurisdictional area, as applicable. CMS and the State Administering Agency must approve any change in the designated service area;

- The organization's commitment to meet all applicable requirements under Federal, State, and local laws and regulations, including provisions of the Civil Rights Act, the Age Discrimination Act, and the Americans With Disabilities Act;
- The effective date and term of the agreement;
- A description of the organizational structure of the PACE organization and information on administrative contacts including the name and phone number of the program director, the name of all governing body members, and the name and phone number of a contact person for the governing body;
- A participant bill of rights approved by CMS and an assurance that the rights and protections will be provided;
- A description of the process for handling participant grievances and appeals;
- A statement of the organization's policies on eligibility, enrollment, voluntary disenrollment, and involuntary disenrollment;
- A description of services available to participants;
- A description of the organization's quality assessment and performance improvement program;
- A statement of the levels of performance required by CMS on standard quality measures;
- A statement of the data and information required by CMS and the State Administering Agency to be collected on participant care;
- The Medicaid capitation rate and the methodology used to calculate the Medicare capitation rate; and
- A description of procedures that that organization will follow if the PACE program agreement is terminated.

Additionally, an agreement may provide additional requirements for individuals to qualify as PACE program eligible individuals in accordance with section § 460.150(b)(4) and may contain any additional terms and conditions agreed to by the parties if the terms and conditions are consistent with sections 1894 and 1934 of the Act and the part 460 regulations.

Additional information about the program agreement can be found on the CMS website at: [http://www.cms.hhs.gov/PACE/06\\_ProviderApplicationandRelatedResources.asp#TopOfPage](http://www.cms.hhs.gov/PACE/06_ProviderApplicationandRelatedResources.asp#TopOfPage).

The program agreement is effective for a contract year and may be extended for subsequent contract years in the absence of a notice by a party (CMS, State Administering Agency, or the PACE organization) to terminate the agreement. The first contract year can extend up to 23 months, that is, to December 31<sup>st</sup> of the year following the effective date of the contract.

CMS or the State Administering Agency may terminate the program agreement at any time for cause, including, but not limited to, uncorrected deficiencies in the quality of care furnished to participants, the PACE organization's failure to comply substantially with the conditions for a PACE program, or non-compliance with the terms of the agreement. The PACE organization may terminate the program agreement after timely notice to CMS, the State Administering Agency and the participants. Notifications shall be made as follows: 90 days before termination to CMS and the State Administering Agency and 60 days before termination to the participants.

[42 CFR §§ 460.6, 460.30(b), 460.32, 460.34, and 460.50]

### **17.5 Effect of Change of Ownership**

CMS requires disclosure of any organizational changes that affect the philosophy, mission, and operations of the PACE organization and impact care delivery to participants. CMS believe that any change in ownership, relationships to another corporate board and to any parent, affiliate, or subsidiary corporate entities, the PACE governing body, its officials, program director, and medical director could result in a substantial impact on the participants and their care. This does not include changes in personnel or a change in the line of reporting of direct participant care staff.

CMS requires any PACE organization that is planning a change in organizational structure to notify CMS and the State Administering Agency, in writing, at least 14 days before the change takes place.

[42 CFR § 460.60(d)(3); 71 FR 71264 (Dec. 8, 2006)]

## Appendix I

### PACE Manual Glossary

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**Adverse Event:** Undesirable clinical outcome resulting from some aspect of diagnosis or therapy, not an underlying disease process.

Examples:

- Postoperative wound infection;
- Hospital-Acquired Delirium (or "sun downing") in elderly patients.

Identifying something as an adverse event does not imply "error," "negligence," or poor quality care. It simply indicates that an undesirable clinical outcome resulted from some aspect of diagnosis or therapy, not an underlying disease process. Postoperative wound infections count as adverse events even if the operation proceeded with optimal adherence to sterile procedures, the patient received appropriate antibiotic prophylaxis in the peri-operative setting, and so on.

**Audit Team:** A group of people comprised of CMS, State Administering Agency staff, or their designees who are assigned to perform a PACE Organization audit.

**Audit:** An external review of a PACE organization's practices and procedures to determine compliance with CMS program requirements.

**Centers for Medicare & Medicaid Services (CMS):** The federal agency that runs the Medicare program and partners with the States to run the Medicaid program.

**Contract Year:** The term of a PACE Program Agreement, which is a calendar year, except that a PACE organization's initial contract year may be from 12 to 23 months, depending on the effective date of program implementation.

**Corrective Action Plan (CAP):** A formal written plan submitted by a PACE organization to CMS to rectify/address deficiencies identified as a result of a PACE Audit.

**Corrective Action Required (CAR):** A term historically used in audit reports requesting a CAP from the PACE organization in response to a deficiency.

**Desk Review:** Review of information or documentation conducted by CMS and the State Administering Agency that is not performed at the PACE site.

**First Trial Period Audit:** First of three on-site yearly audits conducted during the PACE organization's first three years of operation to ensure compliance with the PACE regulations.

**Health Insurance Portability and Accountability Act of 1996 (HIPAA)(Pub. L. 104-191):** Legislation passed in 1996 that addresses security and privacy of health data and requires CMS to establish national standards for electronic health care transactions and national identifiers for providers, health plans, and employer.

**Health Plan Management System (HPMS):** Collects data for and manages the following plan enrollment processes for the MA and Part D programs: application process, bid/benefit package submissions, formulary submissions, marketing material reviews, plan oversight, complaints tracking, survey data, operational data feeds for enrollment and payment, and data support for the Medicare & You Handbook and Medicare website (<http://www.medicare.gov>). HPMS supports these processes for all private plans participating in the MA and Part D programs.

**Interdisciplinary Team (IDT):** A group of knowledgeable clinical and non-clinical PACE center staff, employed or contracted, responsible for the holistic needs of the participant who work in an interactive and collaborative manner in order to control the delivery, quality, and continuity of care for each participant.

**Level II Event:** Unusual incidents that result in serious adverse participant outcomes, or negative national or regional notoriety related to the PACE program; usually used to refer to events that are not at all expected or acceptable (e.g., an operation on the wrong patient or body part).

**MA-only Plan:** A CMS health care managed care offering for Medicare beneficiaries.

**MA-PD:** Medicare Advantage-Prescription Drug Plan CMS health care managed care offering for Medicare beneficiaries that includes prescription drug coverage.

**Marketing Materials:** Materials used to promote the PACE program to enrollees and potential enrollees.

**Medicare Beneficiary:** An individual who is entitled to Medicare Part A benefits or enrolled under Medicare Part B, or both.

**On-site Review:** Audit conducted at the PACE organization's site.

**PACE:** Program of All-Inclusive Care for the Elderly.

**PACE Center:** A facility which includes a primary care clinic, and areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining, and which serves as the focal point for coordination and provision of most PACE services.

**PACE Medicaid Participant:** An individual determined eligible for Medicaid who is enrolled in a PACE program.

**PACE Medicare Participant:** A Medicare beneficiary who is enrolled in a PACE program.

**PACE Organization:** An entity that has in effect a PACE Program Agreement to operate a PACE program under this part.

**PACE Participant or Participant:** An individual enrolled in a PACE program.

**PACE Program Agreement:** An agreement between a PACE organization, CMS, and the State administering agency for the operation of a PACE program.

**PACE Program:** A Program of All-Inclusive Care for the Elderly operated by an approved PACE organization that provides comprehensive healthcare services to PACE enrollees in accordance with a PACE Program Agreement and the part 460 regulations.

**PACE Trial Period:** The first three contract years in which a PACE organization operates under a PACE Program Agreement, including any contract year during which the entity operated under a PACE demonstration or a PACE demonstration waiver program.

**Pharmacy Benefit Manager (PBM):** An entity contracted with a PACE organization to provide management of the Part D drug benefit. Contracted functions can vary and can range from point of sale claims adjudication to processing Part D appeals.

**Plan to Plan Reconciliation (P2P):** The process by which PACE organizations reconcile prescription drug payments made by the PACE organization for participants enrolled in another plan.

**Prescription Drug Event (PDE):** Data which details each drug or claim for a drug that a participant receives under the Part D program.

**Prescription Drug Plan (PDP):** CMS health care offering for Medicare beneficiaries that includes ONLY prescription drug coverage.

**Private Pay:** The individual does not have Medicare or Medicaid to cover the cost of PACE and must use other resources to pay for participation in the program.

**Protected Health Information (PHI):** A term which refers to individually identifiable health information, the disclosure of which is restricted by the HIPAA Privacy Rule.

**Provider:** A commonly used term meant to encompass all health care professionals, except pharmacists, who provide medically necessary health care to enrollees.

**Quality Assessment and Performance Improvement Plan (QAPI):** A tool for achieving the levels of performance on quality standards and guidelines, data and information required by

CMS. This plan is a description of the organization's quality assessment and performance improvement program.

**Quality:** A subjective term for which each person or sector has its own definition. In technical usage, quality can have two meanings: 1. the characteristics of a product or service that bear on its ability to satisfy stated or implied needs; 2. a product or service free of deficiencies.

**Services:** Include both items and services.

**Service Area Expansion Application (SAE):** A request submitted by an existing PACE organization to expand current services into other zip codes, counties, street boundaries, census tracts, blocks, or tribal jurisdictional areas.

**Service Area:** A geographic area approved by CMS and the State Administering Agency in which a PACE organization may accept members. Each PACE organization must be available to all eligible and appropriate individuals within its' service area(s).

**State Administering Agency:** The State agency responsible for administering the PACE Program Agreement.

**State Readiness Review (SRR):** The purpose of this review is to determine the organization's readiness to administer the PACE program and enroll and serve participants. Every applicant must meet all of the requirements of the SRR prior to enrolling participants.